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A critical analysis of New Zealand's *Psychoactive Substances Act*  
2013 and its implementation process

A thesis presented in partial fulfilment of the requirements for the degree of

Doctor of Philosophy

In

Public Health

at Massey University, Albany, New Zealand.

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2017



## Abstract

**Introduction:** In July 2013, the New Zealand Parliament passed the *Psychoactive Substances Act* (PSA), the world's first law to regulate the availability of new psychoactive substances (NPS, "legal highs", LH). Under the "interim PSA regime" 47 products were permitted to be sold subject to new retail and other regulations. In May 2014, the Government abruptly ended the interim regime following public protests. This thesis aims to critically evaluate the PSA and its implementation.

**Methods:** A mixed methods approach combined qualitative and quantitative methods of data collection and analysis. Legal analysis of the PSA and related legislation, and content analysis of parliamentary debates and public submissions were completed. Semi-structured interviews were then conducted with key informants (KI) including politicians, government officials, health professionals, and LH industry actors (n=30). Questions about health perceptions and social acceptability of approved products were added to an annual survey of police arrestees (n=834). Analyses of primary data included thematic analysis of interview transcripts and statistical analysis of data from the arrestee survey.

**Results:** The legal definition of "psychoactive substance" (s. 8, 9(1) PSA) overlaps with other regulatory regimes (e.g. medicines, dietary supplements) resulting in an unclear legal status for some products. Interviewed KIs identified a number of issues with the "interim regime", including the safety of interim products, speed and efficiency of withdrawing problem products, the lack of regulations on price and retail opening hours, slowness of developing regulations for the full PSA regime, and the effectiveness of communicating the new policy to stakeholders and the public. As the market commercialised, the LH industry adopted business and lobbying strategies previously attributed to the alcohol and tobacco sectors, including targeting vulnerable customers. Surveyed police arrestees considered approved synthetic cannabis (SC) products higher health risk and less socially acceptable than alcohol, tobacco and many illegal drugs, reflecting problems with interim product approvals. The ban on animal testing of prospective products is likely to prevent further implementation of the PSA, unless a new political consensus is achieved.

**Conclusions:** The issues experienced during PSA implementation highlight the significant challenges of establishing a legal market for psychoactive products. The time, resources and planning required to successfully implement the PSA may have been underestimated.

## Preface

### **Personal statement**

I studied law in Warsaw (Poland) and Lisbon (Portugal), and graduated with a Master's Degree in Law from the University of Warsaw in April 2013. I also worked as a journalist for a couple of years, including as an individual contractor with the Ministry of Justice in Poland. I completed formal education in media studies, obtaining a bachelor's degree from the National School of Film, Television and Theatre in Łódź (Poland) in September 2011. This varied educational and professional background gives me a unique approach to studying laws, with a particular interest in "law in action", where the focus is on how law works in the real world and how it is applied in society rather than purely how it stands in statutes.

I developed my interest in laws controlling access to illegal drugs during a three-month study visit at the Centre for Legal and Economic Research, University of Porto (Portugal) in 2012. Since then my interest in the field has evolved.

I am originally from Poland, a country in Central Europe particularly hard hit by the problem of new psychoactive substances (NPS), with mass poisoning reported in 2010 and 2015. A "blanket ban" on supply of NPS products implemented in Poland in 2010 has not proved to be a long-term solution to the NPS problem. This raised my interest in alternative legal approaches to the NPS problem. During the 10 months of my internship with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in 2013, my interest in the issue of controlling NPS developed further.

It was June 2013, at the 3<sup>rd</sup> International Multidisciplinary Forum on New Drugs (Lisbon, Portugal), that I first learnt about New Zealand's regulated market approach to new psychoactive substances from a presentation by Associate Professor Chris Wilkins. In March 2014 I applied for a PhD scholarship to study how the New Zealand's market for NPS established under the Psychoactive Substances Act (PSA) 2013 worked in practice.

By the time my PhD study began in June 2014 the interim regulated market established under the PSA had been ended. This unforeseen change in the regulatory environment necessitated substantial changes in the initial PhD research proposal. However, it also raised a new set of questions about what issues and challenges with the PSA had resulted in the abrupt ending of the interim regime. My PhD aimed to investigate and analyse these issues and challenges with the intention of enhancing any future implementation of the PSA and identifying learnings for proposed regulatory regimes for other psychoactive substances.

## **Acknowledgements**

Associate Professor Chris Wilkins and Professor Karen Witten supervised this Thesis and I would like to acknowledge their advice and guidance. In particular, I would like to thank my primary supervisor Associate Professor Chris Wilkins for his comments on drafts of research articles included in this thesis and continuous support in my research, publishing and learning process. I would like to acknowledge the supportive research environment provided by the SHORE and Whāriki Research Centre and the administrative and editing help from SHORE staff Jan Sheeran and Lisa Morice.

This study would not be possible without participants who agreed to share their experiences about implementation of the Psychoactive Substances Act 2013. I am grateful to all study participants, who I cannot acknowledge here by name due to confidentiality reasons. Also, I would like to thank staff from the Ministry of Health for their help with the legislation and feedback provided. Anonymous reviewers of journal articles published during this PhD also provided valuable comments on the manuscripts.

I would like to thank my family for their support and encouragement.

## About dissertation “by publications”

This thesis has been prepared by joining together six journal articles published or submitted for publication during the course of the PhD candidature. It is a “PhD by publication”, where each results chapter constitutes a research article with a structure typical for peer-reviewed journals. It has been written in line with Massey University Guidelines on PhD Thesis by Publication (Massey University, no date).

The thesis works as an integrated whole, with Chapters 1, 2 and 3 outlining the research context and methodology and Chapter 10 synthesising and discussing findings from all published papers. The results chapters (Chapters 4–9) constitute published research papers.

The table below contains information about publications comprising the results chapters of this thesis, and other research outputs published during this PhD. As the author of this PhD thesis, I hold primary authorship of all research papers, with my thesis supervisors and SHORE & Whāriki Research Centre support staff who contributed significantly to the research listed as co-authors. Appendix A contains a detailed statement of contribution to each research paper and other outputs published during this PhD. I have received permission from all copyright holders to reprint journal articles and other outputs in this thesis.

PhD content	Article title and journal, or full reference (if published)	Publication status
Chapter 4	Rychert, M., & Wilkins, C. (2016). What products are considered psychoactive under New Zealand's legal market for new psychoactive substances (NPS, 'legal highs')? Implications for law enforcement and penalties. <i>Drug Testing and Analysis</i> , 8(8), 768-778. Doi: 10.1002/dta.1943	published
Chapter 5	Rychert, M., Wilkins, C. & Witten, K. (2017). Issues with monitoring the safety of psychoactive products under a legal regulated market for new psychoactive substances (NPS) ('legal highs') in New Zealand. <i>Drug and Alcohol Review</i> . Published online 23 Feb 2017. Doi: 10.1111/dar.12507	published
Chapter 6	Rychert, M., Wilkins, C. & Witten, K. (2017). “Lost in translation”: issues with the establishment of a legal market for 'low risk' psychoactive products ('legal highs') in New Zealand. <i>Drugs: Education, Prevention &amp; Policy</i> . Published online 2 Feb 2017. Doi: 10.1080/09687637.2017.1282422	published
Chapter 7	Rychert, M. & Wilkins, C. (2016). Legal high industry business and lobbying strategies under a legal market for new psychoactive substances (NPS, 'legal highs') in New Zealand. <i>International Journal of Drug Policy</i> , 37, 90-97. Doi: <a href="http://dx.doi.org/10.1016/j.drugpo.2016.08.011">http://dx.doi.org/10.1016/j.drugpo.2016.08.011</a>	published

Chapter 8	Rychert, M., Wilkins, C., Parker, K. & Witten, K. Are government-approved “legal highs” perceived to be safer and more socially acceptable than alcohol, tobacco and illegal drugs? Findings from a survey of police arrestees in New Zealand. <i>Drug and Alcohol Review</i> . Forthcoming.	accepted
Chapter 9	Rychert, M. & Wilkins, C. (2015). The challenge of a ban on animal testing for the development of a regulated legal market for new psychoactive substances (NPS) (‘legal highs’) in New Zealand: Issues and options for resolution. <i>International Journal of Drug Policy</i> , 26(12), 1273-1278. Doi: <a href="http://dx.doi.org/10.1016/j.drugpo.2015.08.006">http://dx.doi.org/10.1016/j.drugpo.2015.08.006</a>	published
Appendix G	Rychert, M. & Wilkins, C. (2015) Did we have the wrong debate about Elixinol™ and medicinal cannabis? [Letter]. <i>New Zealand Medical Journal</i> , 128(1521), 69-70.	published
Appendix H	Rychert, M. & Wilkins, C. (2016). Thirty-one psychoactive plants exempted from New Zealand's Psychoactive Substances Act 2013 [Letter]. <i>Addiction</i> , 112(1), 181-182. Doi: 10.1111/add.13526	published
Appendix I (some sections incorporated in Chapter 2, s 2.1, 2.3)	Rychert, M., & Wilkins, C. (2017), <i>New Zealand's pre-market approval regime for 'low risk' new psychoactive substances (NPS, 'legal highs') - a regulatory alternative to prohibition</i> , in: A. Malczewski (Ed.) <i>Monitoring drugs and drug addiction on local level</i> . Warsaw, Poland: Information Centre for Drugs and Drug Addiction. (Published in English and Polish)	published
Appendix K	Rychert, M., & Wilkins, C. (2015). Is the recent ban on animal testing of legal high products a fatal blow to the development of a legal market for ‘low-risk’ psychoactive products in New Zealand? [Letter] <i>Addiction</i> , 110(4), 713-714. Doi: 10.1111/add.12853	published
Appendix L	Wilkins, C., and Rychert, M. (2017) Recent developments with the New Zealand regulated market approach to ‘low-risk’ psychoactive products. <i>Addiction</i> , 112: 34–36. doi: <a href="https://doi.org/10.1111/add.13495">10.1111/add.13495</a> .	published
Appendix M	Wilkins, C., Rychert, M., Byrska, B., Van Hout, M., Corazza, O., & A.Roman-Urrestarazu (2017). “Exploring novel policy responses to NPS and ‘legal highs’ in New Zealand, Poland, Republic of Ireland & the United Kingdom”. <i>Novel Psychoactive Substances. Policy, Economics and Drug Regulation</i> . Ed. Ornella Corazza & Andres Roman-Urrestarazu. Springer Nature, 2017	published

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## List of acronyms

ECJ	European Court of Justice
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EU	European Union
EWA	Early Warning Advisory (UNODC)
EWS	Early Warning System (EU)
IDMS	Illicit Drug Monitoring System (IDMS – NZ)
KI	Key informant
LAPP	Local Approved Product Policy (NZ)
LH	‘Legal highs’
LHI	‘Legal high’ industry
MODA	Misuse of Drugs Act (1971 – UK; 1975 – NZ)
MOH	Ministry of Health
NGO	Non-governmental organisation
NPS	New psychoactive substances
NZ	New Zealand
NZ-ADUM	New Zealand Arrestee Drug Use Monitoring study
NZLC	New Zealand Law Commission
P	Participant
PSA	Psychoactive Substances Act (2013 – NZ, 2016 – UK)
PSAA	Psychoactive Substances Amendment Act (2014 - NZ)
PSB	Psychoactive Substances Bill (i.e. “draft” law, before vote in Parliament - NZ)
PSEAC	Psychoactive Substances Expert Advisory Committee (NZ)
PSRA	Psychoactive Substances Regulatory Authority (NZ)
RSR	Restricted Substances Regime (NZ)
SC	Synthetic cannabinoids
TCDN	Temporary Class Drug Notice (NZ)
TCDO	Temporary Class Drug Order (UK)

UN	United Nations
UNODC	United Nations Office on Drugs and Crime
UK	United Kingdom
WHO	World Health Organization

# Chapter 1: Research context

## 1.1 The challenge of new psychoactive substances (NPS)

The international drug control system managed by the United Nations (UN) aims to limit the use of narcotic and psychotropic drugs to medical and scientific purposes, and to prevent their diversion to illicit channels. The system operates by listing drugs and drug preparations in schedules under the 1961 UN Single Convention on Narcotic Drugs and 1971 UN Convention on Psychotropic Substances (Hallam, Bewley-Taylor, & Jelsma, 2014; Krajewski, 1999). Internationally controlled drugs (120 narcotic and 130 psychotropic drugs as of December 2016 (INCB, 2016a, 2016b)) have certain risks, as identified through examination by the World Health Organization (WHO) (Bewley-Taylor, 2003). The 1988 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances requires that criminal sanctions should apply to illegal supply of internationally scheduled drugs.

The UN drug conventions are not self-executing, which means that they are not directly or immediately enforceable; hence states (parties to the Conventions) pass relevant drug laws to enforce prohibitions on supply and possession of drugs. As it is a general principle of criminal law that criminal offences be clearly defined (*nullum crimen sine lege certa*), controlled drugs need to be named or otherwise clearly specified in national drug control laws. This is done by listing drugs on a substance-by-substance basis in the attachments to national drug laws (i.e. scheduling on a domestic level), and sometimes by tightly defining groups of substances based on their structural similarity to chemical compounds which are already under control (so-called generic definitions) (EMCDDA, 2015c). This long-established mechanism for drug control has been challenged by the emergence and dynamic spread of new psychoactive substances (NPS).

NPS, sometimes also known as “legal highs”, are recreational drugs which are not controlled under the international drug control system but which may pose a public health threat (UNODC, 2013a). In the last ten years or so, the number of NPS introduced to the market has risen dramatically and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) currently monitors over 560 different NPS compounds, of which more than 70% have been detected in the last five years (EMCDDA and Europol, 2016b). The number of new drugs overwhelms any attempts to schedule compounds on a substance-by-substance basis. Procedures for international scheduling have been described as “too time-consuming to prevent widespread abuse before bringing a substance under control” (UN, 2014). Scheduling on a domestic level also requires time and financial resources as the substances have to be assessed

for harmfulness and prohibition orders need to pass through legislative assemblies. By the time a given compound is prohibited, a new substance will have appeared on the market as new synthetic drugs can be quickly synthesised by introducing slight modifications to chemical structures of existing compounds. This “cat and mouse game” between NPS producers and national authorities is considered a major challenge in designing a comprehensive and effective policy response to the NPS phenomenon (Brandt, King, & Evans-Brown, 2014; Seddon, 2014).

### **1.1.1 The evolution of NPS phenomenon and definitions**

The appearance of new substances which are not covered by the international drug control system is not a new phenomenon (Brandt et al., 2014; King & Kicman, 2011), but until early 2000 it was limited to a handful of substances and mostly to traditional illegal drug markets. This section explains how the evolution in the manufacture and distribution of NPS over the last 50 years has influenced changes in the way the NPS phenomenon is defined. It concludes with the definition of NPS used for the purposes of this PhD thesis.

The NPS phenomenon can be traced back to the 1960s, when ring-substituted phenethylamines such as STP (2,5-dimethoxy-4-methamphetamine) first appeared on drug markets in the UK (Phillips & Mesley, 1969). In the 1980s, following public health concerns associated with new derivatives of  $\alpha$ -prodine and fentanyls (these heroin substitutes were highly potent and the by-product in  $\alpha$ -prodine synthesis-induced Parkinson’s disease (King & Kicman, 2011)), the very first definition of “new drugs” was proposed (Henderson, 1988). It defined NPS as “analogues of compounds with proven pharmacological activity manufactured by underground chemists for sale on the street” (Baum, 1985). It was around this time that the question of how to control NPS was first raised (Baum, 1985).

In the 1990s, following publication of Alexander and Ann Shulgin’s books PiHKAL (short for “Phenethylamines I Have Known and Loved” (Shulgin & Shulgin, 1991)) and TiHKAL (short for “Tryptamines I Have Known and Loved” (Shulgin & Shulgin, 1997)), the new drugs phenomenon gained new momentum. Despite the short lifespan of most ring-substituted phenethylamines and tryptamines (Brandt et al., 2014; King & Kicman, 2011), their rapid development in illicit drug markets raised public concern. In 1997, in response to these concerns, the European Union (EU) adopted the *Joint Action concerning the information exchange, risk assessment, and control of new synthetic drugs*. The document contained the first formal definition of “new synthetic drugs” (NSD), i.e. “synthetic drugs which are not scheduled in 1971 UN Convention on

Psychotropic Substances, and which cause a comparable serious threat to public health (...) and which have a limited therapeutic value” (Council of the European Union, 1997).

Around 2000 a major change in production and distribution of “new drugs” occurred, heralding what is now referred to as “the NPS phenomenon” (Brandt et al., 2014; King & Kicman, 2011). NPS were increasingly being manufactured by legitimate chemical companies located in Asia (King & Kicman, 2011) and shipped to consumer markets where they were openly sold in head shops and online. The change in manufacturing and marketing processes was accompanied by increased diversification of the market into new drug families, including piperazine derivatives (e.g. BZP), cathinone derivatives (e.g. mephedrone), synthetic cannabinoids (e.g. “Spice” brand) and plant products (e.g. *salvia divinorum*). The UNODC definition of NPS accommodated these changes and it is now accepted that the term NPS covers both *synthetic and natural substances* which are not scheduled under the UN Conventions and *which may pose a public health threat* (UNODC, 2013a). It is important to note that some of these substances were synthesised decades ago or have been used by indigenous populations for centuries; hence the word “new” in the term NPS refers to “newly misused” and “newly available”, and not necessarily “newly discovered” (EMCDDA and Europol, 2007; King & Kicman, 2011; UNODC, 2013a).

NPS are also referred to as “legal highs”, “research chemicals”, “plant food”, “bath salts”, “party pills”, and “herbal incense” (Brandt et al., 2014; F. Dunne, Jaffar, & Hashmi, 2015), with many of the informal terms invented by distributors to circumvent national laws by suggesting the products are not intended for human consumption and to emphasise their legality (Brandt et al., 2014; Rosenbaum, Carreiro, & Babu, 2012). The term “legal high”, traditionally used to describe herbal psychoactives, has been particularly problematic. Corazza, Demetrovics, van den Brink, and Schifano (2013) suggested that it should not be used in academic debate. However, the term is used in this thesis to distinguish the broad concept of NPS as explained above (i.e. substances not controlled internationally) from substances which are not prohibited under *domestic* laws, as since the emergence of the NPS phenomenon many countries have implemented legal measures to control NPS compounds or their classes at the national level (these are further discussed in section 1.2).

Scheduling of NPS at the international level further adds to the complexity of the phenomenon and its definition. For example, nine substances which were not internationally controlled when this PhD study commenced (i.e. AH-7921, 25B-NBOMe, 25C-NBOMe, 25I-NBOMe, mephedrone, BZP, JWH-018, AM-2201, MDPV, methylone) were subsequently scheduled under the UN conventions (UNODC EWA, 2015). As scheduled drugs, they do not technically fall under the NPS

definition anymore, but in practice they are still referred to as NPS (e.g. EMCDDA and Europol (2016b)). As used in this thesis, the term NPS covers any psychoactive substance appearing on the market around or after the year 2000, even if subsequently scheduled under the UN system.

### **1.1.2 NPS market characteristics**

In the last ten years or so, the number of NPS identified globally has been on the rise, with over 700 NPS reported to the UNODC since 2008 (UNODC, 2017). The figure now well exceeds the number of illicit drugs and preparations scheduled in the UN Conventions (currently 250 compounds). Reports of new NPS received by the UNODC reporting system more than doubled over the period 2009–2013, with most new substances identified in Europe over the last decade (UNODC, 2014). The EU Early Warning System (EWS) now monitors over 620 NPS (EMCDDA, 2017), and in 2014 the rate of detection in Europe reached two new NPS per week (EMCDDA, 2015b). In 2016, the rate of detection of NPS in Europe dropped to one NPS per week (EMCDDA, 2017). However, the market continues to develop dynamically (UNODC, 2015, 2016, 2017) and the overall number of NPS continues to grow (EMCDDA, 2017) (Figure 1). It is a global phenomenon, with over 100 countries and territories in the world having reported at least one NPS (UNODC EWA, 2017b).

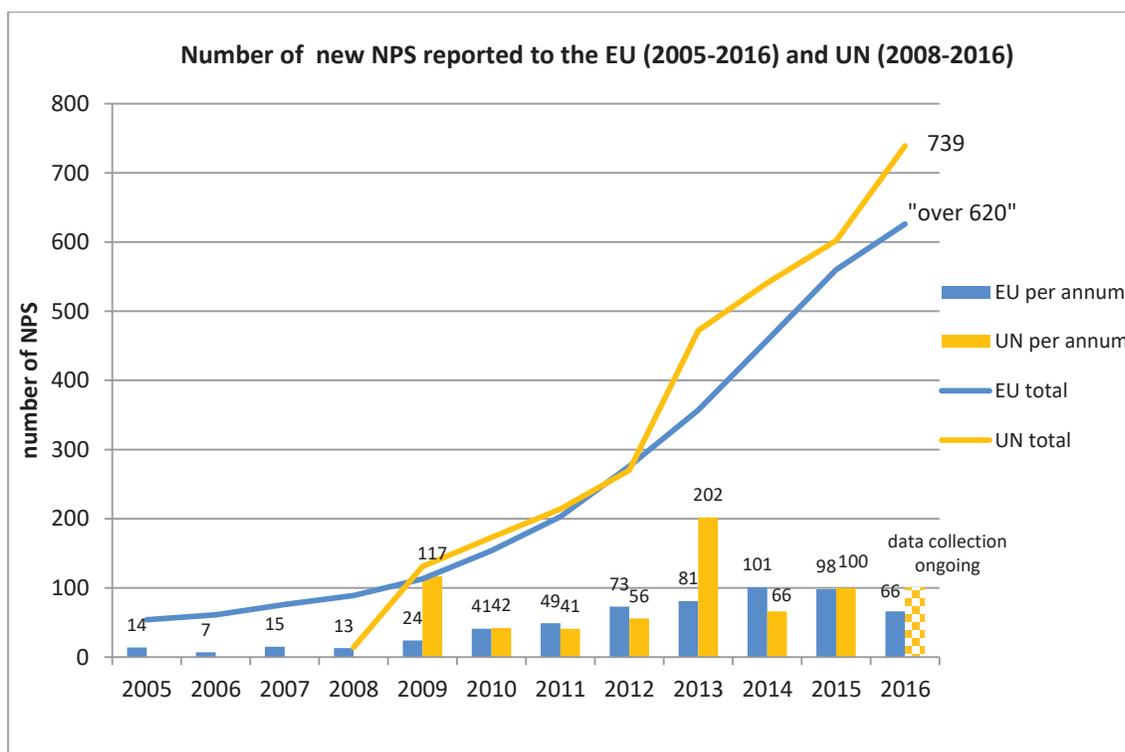


Figure 1: Number of NPS reported to the EU and UN

Sources used to compile data: UNODC, World Drug Report 2015, 2016, 2017; EMCDDA, European Drug Report 2016, 2017; EMCDDA, Annual Reports on the implementation of Council Decision 2005/387/JHA 2005-2014; EMCDDA & Europol, Drugs Markets Report 2016.

The term NPS covers several substance groups and the categorisation of NPS is evolving. The UNODC currently distinguishes nine NPS groups based on chemical structure: (1) synthetic cannabinoids (sold as “legal alternatives” to cannabis); (2) synthetic cathinones (sold as “legal alternatives” to illegal stimulants such as MDMA, amphetamine or cocaine); (3) phenethylamines (e.g. ‘2C series’); (4) piperazines (often include “failed pharmaceuticals”); (5) aminoindanes; (6) tryptamines; (7) ketamine and phencyclidine-type substances; (8) plant-based substances (e.g. Khat, Kratom); and (9) “other NPS” (including synthetic opioids) (UNODC EWA, 2017a). This classification is consistent with academic literature on chemical classes of NPS (Miliano et al., 2016). However, there is no internationally accepted categorisation and the EMCDDA, for example, adopts a more detailed approach, with distinct categories for groups of substances such as arylcyclohexylamines (e.g. methoxetamine) or arylalkylamines (e.g. bromo-dragonfly) (EMCDDA and Europol, 2016a). An increasing number of newly-identified NPS compounds (e.g. fentanyl derivatives and new synthetic sedatives) do not belong to any of the

chemical groups defined in previous years, illustrating the dynamic nature of the NPS market (UNODC, 2016, 2017). Appendix B contains a table of all NPS compounds mentioned in this thesis and their categorisation into chemical groups.

An alternative categorisation approach to NPS is by their pharmacological effects. The two most common “effect” groups include synthetic cannabinoid receptor agonists and synthetic stimulants (Figure 2).

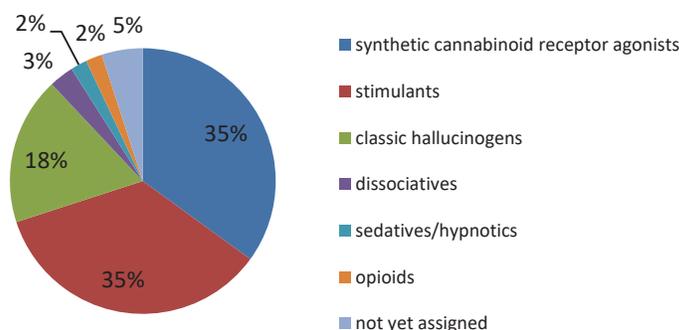


Figure 2: NPS groups categorised by pharmacological effect (data up to 2015), source: UNODC EWA (2017a)

Both global and the EU monitoring systems identify synthetic cannabinoids (SC) as the most frequently reported NPS substance group (EMCDDA, 2015b; UNODC, 2015, 2016). Sold and used as legal alternatives to internationally controlled cannabis and its active ingredient  $\Delta^9$ -tetrahydrocannabinol (THC) (Griffiths, Sedefov, Gallegos, & Lopez, 2010; L. A. King, 2014; Papanti, Orsolini, Francesconi, & Schifano, 2014), SC products have been defined as a case study for analysing new challenges to existing modes of drug control (Griffiths et al., 2010). Indeed, part of the NPS phenomenon, including the appearance of NPS as “legal alternatives” to illicit drugs, has been explained by interplays between traditional prohibitive drug policies and changes in purity and price on the illicit drug markets (Brandt et al., 2014; F. Dunne et al., 2015; Evans-Brown & Sedefov, 2016).

The way NPS are manufactured, distributed and marketed is distinct from traditional channels for illegal drugs, with synthetic NPS often manufactured in legitimate chemical companies in Asia and shipped to consumer markets in Europe, the US, Australia and New Zealand, and then sold from so-called head shops and online (King & Kicman, 2011). The marketing and distributional capacity of the Internet has been evidenced in numerous studies (e.g. Bruno, Poesiat, & Matthews, 2013; Corazza et al., 2011; Davies et al., 2010; Kavanagh, Grigoryev, Savchuk, Mikhura, & Formanovsky, 2013; Meyers et al., 2015; Schmidt, Sharma, Schifano, &

Feinmann, 2011; Schneir et al., 2014). This literature presents a distinct picture of NPS markets, where geographical barriers do not constrain trade and legal restrictions in consumer countries have a limited impact on manufacturing processes in source countries (Khey, Stogner, & Miller, 2014). When NPS are not controlled in consumer countries, they may be sold as legal products (hence called “legal highs”) (Griffiths, Evans-Brown, & Sedefov, 2013; Khey et al., 2014; Winstock & Wilkins, 2011).

Products containing NPS have been marketed in diverse forms, i.e. as recreational “legal highs” commercialised in bright packages, as “research chemicals” aimed at online communities exploring psychoactive effects (i.e. psychonauts), and as “food supplements” marketed to improve brain function and physical performance (Brandt et al., 2014; EMCDDA, 2015b; Griffiths et al., 2013). In addition to these new presentations of synthetic drugs is the traditional “designer drugs” label, where NPS appear on illicit drug markets either in their own right or as ecstasy/amphetamine. Some NPS first marketed as “legal highs”, and so not controlled under international and national drug control laws (e.g. mephedrone, MDPV), have stayed on the market following imposition of legal controls and became part of the illicit drug market landscape (EMCDDA, 2015a; UNODC, 2016).

In terms of prevalence, the latest European data show that 8% of young adults (defined as 15–24 years old) have tried NPS in their lifetimes. This compares to the 13.3% lifetime prevalence for natural cannabis among young adults (defined as 15–34 years old) in Europe (EMCDDA, 2016a). However, there are limitations in the prevalence data of NPS, including the difficulty in designing survey tools for capturing NPS use, limited knowledge by users about the substances they use, and constant changes in the market which challenge comparisons over time and across countries and regions (EMCDDA and Europol, 2016b; UNODC, 2016). These are some of the reasons why there is no estimate of NPS prevalence at a global level (UNODC, 2016).

### **1.1.3 Health risks associated with NPS use**

Knowledge about health effects of NPS use is limited, but the increasing number of case reports and studies on NPS-related adverse health events (including systematic analyses) add to the understanding of their health impacts. The sheer number of different NPS compounds mean variations in psychopharmacological and toxicity profiles (for categorisation of NPS by pharmacological effect see Figure 2 above). Babor, Caulkins, et al. (2010) use a narrow “health frame” in their classification of harms associated with illicit drugs, which is adopted below to review the as yet limited evidence about harms associated with NPS. Five classes of morbidity

and mortality outcomes are discussed: (I) overdose; (II) other injuries, e.g. accidents and suicides; (III) non-communicable physical disease; (IV) mental disorders; and (V) infectious disease.

The high potency of many synthetic NPS, which may be active at doses lower than traditional drugs, is a major health risk to users as it can increase the risk of overdose (Brandt et al., 2014). For example, fentanyl analogues which appeared on the California drug market as heroin substitutes in the early 1980s were up to 1000 times as potent as heroin, and this contributed to over 110 overdose deaths (Henderson, 1988). In a more recent development, several outbreaks of NPS-related deaths were reported. For example, the EMCDDA reports in the last two years (2014-2016) have identified numerous deaths associated with the use of alpha-PVP (over 100 deaths), acetylfentanyl (32 deaths) (EMCDDA, 2016a), MDMB-CHMICA (28 deaths) (EMCDDA, 2017) and 25I-NBOMe (3 deaths) (EMCDDA, 2014). A recent systematic review of SC-related adverse events identified “at least 26 deaths” associated with SC use (Tait, Caldicott, Mountain, Hill, & Lenton, 2016). Mass poisonings, although rare, have also been reported (EMCDDA and Europol, 2016b). For example, in mid-2015 hospitals in Poland recorded over 200 emergency presentations linked to use of SC products in less than a week (EMCDDA, 2016a).

The role of NPS in overdose, however, can be difficult to determine, particularly when NPS are used in combination with other drugs (UNODC, 2016), or when analytical confirmation of NPS use is not available (e.g. EMCDDA, 2014). A British review of criminal casework where NPS were involved found that only 7% of all drug deaths involved NPS as sole factors (Elliott & Evans, 2014). Some death reports refer to suicidal deaths rather than accidental overdoses. For example, Elliott and Evans (2014) found high prevalence of cathinone drugs (41%) in hangings and other mechanical suicides in their analysis of post-mortem cases. Kriikku, Rintatalo, Pihlainen, Hurme, and Ojanperä (2015) also found high suicide rates (24%) among MDPV-positive post-mortem cases in Finland.

Consumption of any psychoactive drug may result in adverse health outcomes, even when the toxicity profile appears low risk. The intoxicating effects sought by drug users may lead to accidents (e.g. vehicle accidents) and facilitate assaults (Babor, Caulkins, et al., 2010; Kleiman, 1992). For example, a case study analysis of signs of impairment documented by the police in Germany concluded that “consumption of synthetic phenethylamines can lead to impairments similar to MDMA which can affect driving behaviour” (Maas, Wippich, Madea, & Hess, 2015). However, the contribution of NPS intoxication to driving impairment remains understudied due to the lack of psychomotor studies of specific compounds (Kriikku et al., 2015). For similar

reasons, the relationship between the use of NPS and violence is yet to be established. Agitation is one of the symptoms associated with the use of SC (Hermanns-Clausen, Kneisel, Szabo, & Auwärter, 2013; Kronstrand, Roman, Andersson, & Eklund, 2013) and cathinones (Prosser & Nelson, 2012), but the link to violence (Michael et al., 2014) requires further study. The legal or semi-legal status of NPS suggests that the level of systemic violence (i.e. violence associated with aggression in the drug trade (Goldstein, 1985)) will be lower compared to traditional illicit drug markets.

The novelty of the NPS phenomenon does not allow for a comprehensive assessment of long-term health effects in relation to the type of drug and mode of administration (Babor, Caulkins, et al., 2010). Outcome studies of long-term use of certain illicit drugs by certain modes of administration (e.g. pulmonary function deterioration due to smoking natural cannabis) may provide some indication about the likely long-term effects of specific NPS (e.g. long term effects of smoking SC). Similarly, the established link between injecting drugs and infectious diseases (Hagan et al., 2001; Pouget, Hagan, & Des Jarlais, 2012; Strathdee et al., 2001; Thorpe et al., 2002) suggests injecting NPS may be associated with an elevated risk of blood-borne diseases such as HIV, hepatitis B virus (HBV) or hepatitis C virus (HCV). However, case-by-case evaluations are needed to assess long-term health effects of using specific compounds. Data about long-term effects and incidence of non-communicable physical diseases are available mostly for herbal NPS, which have long been used by indigenous populations of specific world regions. For example, long-term khat use has been linked with cardiovascular disorders and identified as a risk factor in heart failure (El-Menyar, Mekkodathil, Al-Thani, & Al-Motarreb, 2015).

Associations between NPS use and mental disorders may be discussed in terms of psychiatric co-morbidity (e.g. psychosis, anxiety, and depression) and substance dependence itself (Babor, Caulkins, et al., 2010; WHO, 2015). While research on the dependence potential of NPS compounds is limited, emergency departments are a source of information about neuropsychiatric adverse outcomes following NPS consumption. For example, a review by Van Amsterdam, Brunt, and Van Den Brink (2015) concluded that SC may have higher psychosis-inducing potential than natural cannabis, i.e. may cause more frequent and more severe unwanted negative effects. This has been attributed to the high potency of SC and absence of cannabidiol (CBD) which acts as a protective factor against THC. There is also evidence that synthetic cathinones can trigger psychotic episodes, with higher risk among users with concurrent psychiatric disorders (Miotto, Striebel, Cho, & Wang, 2013).

Overall, the major risk with NPS use is the unknown psychopharmacological and toxicity profiles of these substances, most of which have never been tested in humans before their appearance on the market (Brandt et al., 2014; Zamengo, Frison, Bettin, & Sciarrone, 2014). Data from national poisons centres, emergency departments and online reports of users' experiences often provide the first information about adverse effects of specific compounds (Khey et al., 2014; Wood & Dargan, 2012), with some of the common problems including anxiety, paranoia, hallucinations, seizures, hyperthermia and cardiotoxicity (Tait et al., 2016; Zamengo et al., 2014). In addition, the actual active ingredients of NPS products are often unknown, as they may be adulterated and/or mislabelled (Ayres & Bond, 2012; Baron, Elie, & Elie, 2011; Zamengo et al., 2014).

## **1.2 New policy responses to NPS**

The number of NPS and uncertainties about their health and social impacts overwhelm any attempts to schedule compounds on a substance-by-substance basis. In recent years, a number of countries have implemented new policy and legislative responses to address the NPS challenge (EMCDDA, 2015c; King, 2013). Understanding the wide range of legislative responses adopted in different countries to address the dynamics of the NPS market has been identified as key in designing and coordinating an effective global response to NPS (UNODC, 2016).

The EMCDDA (2015c) has categorised novel responses to NPS adopted in EU countries into three groups, based on the dimension, source of legal provisions: (1) responses that extend existing drug laws and processes (including generic and analogue definitions); (2) responses where other existing laws are applied to NPS, such as consumer safety or medicines legislation; and (3) entirely new NPS-specific laws.

For the purpose of reviewing innovative policy responses to NPS adopted globally, I extended this categorisation by adding two new dimensions: (1) the scope of NPS provisions (i.e. whether legal measures aim to impose control over one specific compound, a group of compounds or all NPS, including compounds not yet developed); and (2) the restrictiveness of NPS laws with respect to supply (i.e. whether laws aim to impose controls by prohibition or by regulation of the market).

This framework helps illustrate how new policy responses differ from traditional prohibitive drug policy measures (i.e. drug laws controlling individually scheduled compounds by means of prohibition), and how the New Zealand response to NPS stands out from other responses (i.e. NPS law controlling all NPS compounds by means of market regulation). Figure 3 shows how the three dimensions (i.e. source of law, scope of NPS provisions and the restrictiveness of legal control) fit within the spectrum of “innovative” policy responses to NPS:

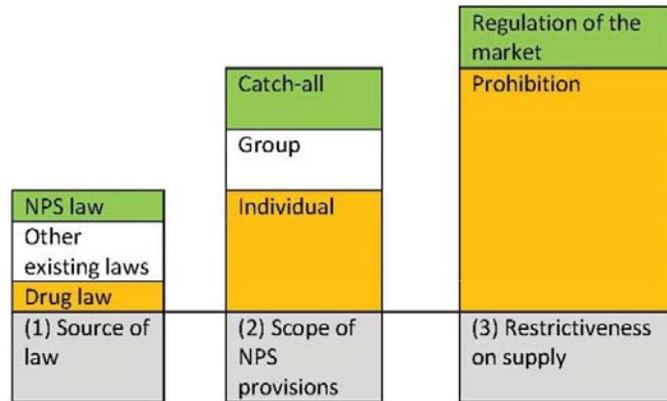


Figure 3: Framework for the review of national responses to NPS

In the remaining sections of this chapter the framework will be used to review the major groups of innovative policy responses to NPS: (1) rapid and emergency procedures; (2) generic, analogue and other group definitions; (3) application of other existing laws to prohibit the sale of “legal highs”; and (4) “blanket bans” on NPS supply. Figure 4 illustrates how these policy responses fit into the proposed framework.

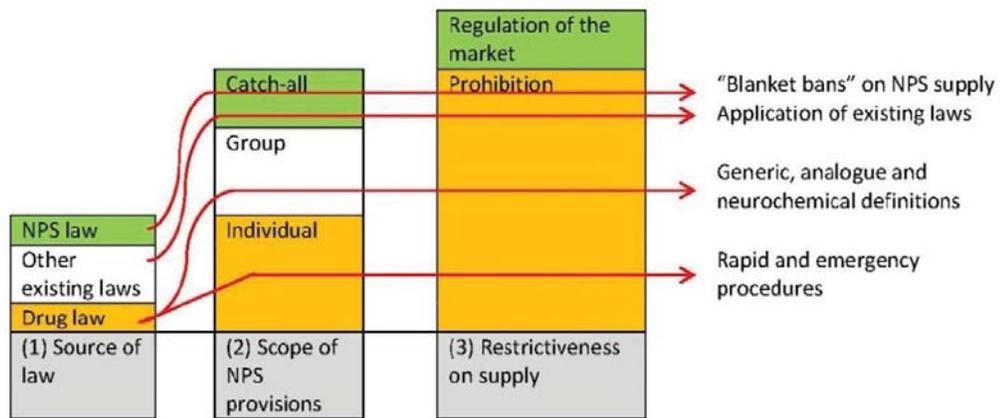


Figure 4: Framework for the review of national responses to NPS, with examples.

### 1.2.1 Rapid and emergency procedures

Under the proposed framework the closest to traditional prohibitive drug law policies are so-called rapid and emergency procedures. These policy responses aim to accelerate the process of bringing specific compounds under state control. “Rapid scheduling” procedures allow for permanent scheduling of NPS in a timeframe shorter than for the standard scheduling of drugs. For example, in Sweden the government can make urgent drug law amendments which enter into force the next day (Hughes & Blidaru, 2009). “Emergency scheduling”, on the other hand, brings NPS under the state’s control for a limited time while their risks are assessed. For example, in 2011 the UK and New Zealand introduced mechanisms for the rapid issuing of so-called Temporary Class Drug Orders (TCDO, in UK) and Temporary Class Drug Notices (TCDN, in NZ). In both countries these controls prohibited supply-related behaviours of “interim scheduled” drugs for a period of 12 months (with a further 12-month extension possible). A similar “emergency scheduling” mechanism was included in the 1961 and 1971 UN Conventions, but has hardly ever been used (UN, 2014).

While emergency and rapid procedures significantly speed up the process of bringing substances under state control, they may also accelerate rapid developments in the NPS market thus potentially reinforcing the “cat and mouse game”. Rapid procedures have also been criticised for lacking evidence-based risk assessment of scheduled substances, while emergency procedures have been criticised for their strong presumption that a temporary controlled substance will be banned permanently (Birdwell, Chapman, & Singleton, 2011). Following its introduction in New Zealand, the TCDN mechanism was subsequently assessed as unsustainable as the two-year ban was unlikely to provide sufficient time for risk evaluation (Wilkins et al., 2013), and it was abandoned following passage of the Psychoactive Substances Act (PSA) in 2013.

### 1.2.2 Generic, analogue and neurochemical definitions

In an attempt to impose controls *before* drugs appear on the market, a number of countries have included broad group definitions in their national drug laws. This includes the so-called generic and analogue definitions, first implemented as early as 1964 (generic controls, UK) and 1986 (analogue controls, US) respectively. While generic definitions cover clusters of substances precisely defined by their similarity in chemical structure to a known illicit drug (Van Amsterdam, Nutt, & Van Den Brink, 2013), analogue definitions address more general aspects of chemical similarity to a known illicit drug (Hughes & Blidaru, 2009). In an attempt to capture groups of

compounds, the chemical term “derivative” has also been used in drug legislation. While it rarely causes definitional problems in chemistry, its usage in legal practice has been problematic (King, Ujváry, & Brandt, 2014), with some arguing that a compound can be considered a derivative only if it can be converted into another compound in a single reaction (Phillips, 1973), while others (including the US legal practice) accept several reaction stages (King et al., 2014). In a more recent policy development, *ex ante* group controls have been imposed by means of the so-called “neurochemical approach”. For example, the US Synthetic Drug Abuse Prevention Act 2012 defines all synthetic cannabinoids as *any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist (...)*, and this is further narrowed to five groups of SC generically described by the chemical characteristics of their structural class (UK NPS Review Expert Panel, 2014).

While all these solutions efficiently capture large groups of substances by anticipating future modifications of known compounds, they have received criticism on legal and practical grounds, such as: (1) the broad scope of criminal drug controls may hinder development of new medicines and increase administrative burden on the chemical and food industries, as well as academic research; (2) generic definitions are difficult to comprehend and the scope of analogue definitions is difficult to predict, which may violate the principle of legality (the rule that nothing is punishable without clearly defined penalty provisions); and (3) substances with no pharmacological effect whatsoever may be prohibited under these laws (thus drug offences may not be correlated with the harmfulness of the substance), while other harmful substances may remain outside the scope of definitions (King, 2013; King, Nutt, Singleton, & Howard, 2012; Van Amsterdam et al., 2013).

### **1.2.3 Application of existing administrative laws**

In another policy response, national authorities have applied existing laws and regulatory regimes to ban supply of NPS products, including medicines and pharmaceutical laws, food safety regulations, consumer protection laws, and import/export laws. Products subject to these regulations need marketing authorisation before being allowed on the legal market (medicines), or need to comply with general product safety requirements (other consumer products). These administrative frameworks have been used to prohibit trade in NPS. For example, BZP (in Spain), mephedrone (in Finland), “Spice” (in the UK) were all first controlled as medicines and their sale prohibited on the grounds of the unlawful sale of “unsafe medicinal products” (Hughes & Winstock, 2012). In Poland, consumer protection legislation was applied to close down over 1,200 legal high outlets in October 2010 (Hughes & Malczewski, 2011).

In a review of these innovative policy responses, Hughes and Winstock (2012) concluded that these controls appeared to achieve the objective of curtailing open sale of NPS products across Europe. Nevertheless, they remained concerned about practical challenges, including financial constraints on agencies responsible for enforcement of consumer protection and medicines laws. Other authors have suggested that administrative laws may be circumvented by a disclaimer “not for human consumption” (Birdwell et al., 2011). Sheridan, Atmore, and Russell (2012) also pointed out that the practice brings into question the integrity of the law in falsely labelling NPS as “medicines”, as the substances are used to induce pleasure and not therapeutic effects. Indeed, in its 2014 judgement the Court of Justice of the European Union (ECJ) ruled that recreational products containing synthetic cannabinoids do not fall under the legal term “medicinal product” (European Court of Justice, 2014a). Consequently, their open sale in EU countries can no longer be prosecuted on the grounds of the unlawful sale of unsafe medicinal products (European Court of Justice, 2014b).

#### **1.2.4 “Blanket bans” on NPS supply**

Most recently, a so-called “blanket ban” approach has attracted considerable international attention. This approach prohibits supply-related activities (and sometimes possession) of any substance with psychoactive properties and hence covers all NPS compounds. Ireland was the first country to implement the solution (July 2010), introducing criminal sanctions on the supply of any “psychoactive substance” (Kavanagh & Power, 2014; Ryall & Butler, 2011). In the same year Poland modified the legal definition of “substitute drug” in its national drug law to cover all NPS, and imposed high administrative fines on suppliers of all substances which are “used instead of illicit drugs or for the same purposes” (Kapka-Skrzypczak et al., 2011). Modelling the Polish approach, Romania criminalised supply of NPS with sanctions including a mandatory minimum prison sentence (Hughes & Griffiths, 2014). In Australia, a blanket ban on importation of NPS has been implemented at the federal level and supply is prohibited in a number of states. In 2016, the UK followed suit by passing the UK Psychoactive Substances Act (UK PSA) 2016.

A central criticism of blanket bans is they prohibit sales of any psychoactive product, including where there is no evidence of harm from substance use. This stretches the credibility of the drug control system as a mechanism for protecting public health (Hughes & Winstock, 2012), and raises questions about the acceptability of these laws (Ryall & Butler, 2011). Hughes and Griffiths (2014) agreed that blanket ban approaches remain in a legally “unclear area”. The concept of “psychoactivity” has raised terminological questions when used in legal definitions (Brandt et al., 2014). In the UK, for example, the new definition of “psychoactive substance” included in

the UK PSA 2016 has been criticised for being “extraordinarily broad” (Stevens, Fortson, Measham, & Sumnall, 2015) and “conceptually fraught” (Reuter & Pardo, 2017). Reuter and Pardo (2017) went so far as to state that “operationalising psychoactivity as a usable concept for legal control purposes is extremely difficult, perhaps impossible”.

### **1.2.5 Summary of issues with prohibiting NPS on national level**

The innovative policy responses to NPS reviewed in sections 1.2.1–1.2.4 are all prohibitive in nature, i.e. they aim to eliminate or suppress the market for NPS. They all come with some successes, but also significant limitations. Emergency scheduling and temporary bans, although significantly speeding up the process of bringing NPS under state control, have had the unintended consequence of accelerating developments on the NPS market. Generic, analogue and neurochemical definitions included in national drug laws raise other concerns: their application requires expert chemical knowledge and there are uncertainties around the degree of similarity needed to classify specific compounds as analogues. Under these regimes some harmful substances remain outside the legislative framework, while others (less harmful) may be prohibited. The application of other existing civil laws to control the NPS market does not fit their original purpose. This practice was challenged in a 2014 ECJ judgement (joint cases C-358/13 and C-181/14), which necessitated changes in the practice of prosecuting NPS cases in a number of European countries (EMCDDA and Eurojust, 2016). Finally, while “blanket bans” have proved effective in closing down “legal high” stores in some countries (Hughes & Griffiths, 2014; Hughes & Malczewski, 2011), unintended consequences of this approach, including the impact on the online drug markets or the extent of covert sales, are yet to be explored. These responses also raise concerns of a legal nature in relation to applying the definition of “psychoactivity” in practice.

The problematic nature of prohibition-based responses adopted in other countries became the driver for New Zealand’s pre-market approval regime, an alternative legal control approach based on regulation rather than prohibition.



## **Chapter 2: New Zealand's regulated market response to NPS**

New Zealand's response to NPS sits in stark contrast to prohibitive policy approaches adopted in other countries. In July 2013, New Zealand's Parliament passed the Psychoactive Substances Act (PSA), which established the world's first regulated legal market regime for NPS. Under the PSA product sponsors can gain government approval to legally manufacture and sell their products if they demonstrate through toxicology and clinical trials that the products are "low risk" (New Zealand Parliament, 2013a; Wilkins, 2014a). This new regulated market approach received significant international attention as a "long-term" (UN, 2013), balanced (EMCDDA, 2015e), and "bold and innovative" solution to the NPS phenomenon (UK NPS Review Expert Panel, 2014) which could potentially be adopted in other countries (Seddon, 2014).

This chapter outlines the historical background to the PSA and describes how the regulated market is intended to work under the PSA regulatory framework. Section 2.3 contains a summary of issues raised during consultation stage for the Psychoactive Substances Bill (PSB), i.e. the results of content analysis of written submission to the PSB and thematic analysis of parliamentary transcripts completed by me as part of the "formative research" process. The chapter then explains how the law was implemented during the "interim regime" between July 2013 and May 2014. Finally, the existing academic literature on the PSA and its implementation is reviewed, knowledge gaps identified and the research focus of this PhD explained, with specific research objectives outlined in s. 2.7.

### **2.1 The early emergence of legal highs in New Zealand**

New Zealand has been at the forefront of the legal high phenomena with a legal high industry (LHI) operating since the early 2000s, when a range of products containing the synthetic stimulants benzylpiperazine (BZP) and trifluoromethylphenylpiperazine (TFMPP) appeared on the market (Sheridan & Butler, 2007; Wilkins & Sweetsur, 2010). So-called BZP "party pills" were marketed on a commercial scale, with much of the manufacturing happening in India and China, thanks to the then unregulated international status of BZP (Szalavitz, 2015). The party pills varied in strength and quality, and were sold from counter culture stores and increasingly from local convenience stores (Sheridan & Butler, 2007). BZP/TFMPP party pills soon gained popularity among a wide group of users and it is estimated that by 2004 approximately five million legal BZP/TFMPP party pills had been sold on the market, amounting to sales of 24 million New Zealand Dollars (NZD) per year (Wilkins & Sweetsur, 2010).

In response to the growing popularity of BZP party pills and uncertainties around potential health impacts, a new regulatory regime was established by an amendment to the Misuse of Drugs Act (MODA). The so-called “Restricted Substances Regime” (RSR, also known as “Schedule D”) allowed controlled sale of substances assessed by the government to be “low risk”, and BZP was immediately included in this new schedule (New Zealand Parliament, 2005). The RSR imposed some restrictions on the newly-regulated market, such as an age limit on sale (i.e. 18 years or older), limits on advertising and a ban on giving away free product samples (Sheridan & Butler, 2010). The legal high industry continued commercial sale of their products under this regulatory regime. More detailed government regulations for the RSR, including product quality standards and maximum dose limits, were anticipated. However, their introduction in late 2008 didn’t impact on the BZP market as it had been brought to an end before these restrictions took effect. In 2008, based on new evidence of BZP-related health harms, including from previously commissioned government research (e.g. I. Thompson et al., 2006), BZP was scheduled as a Class C drug under MODA and thus became a prohibited substance.

The “legal highs” industry responded to the ban on BZP by shifting production to non-BZP party pills and SC, which were not controlled by any legislation (Wilkins et al., 2013). Similarly to the early BZP products, SC were increasingly sold from convenience stores without any regulatory restrictions. Again, little was known about their health impacts and the speed of government response was limited due to the slowness of assessment and scheduling processes. Between 2011 and 2013, a number of products were taken off the market by means of Temporary Class Drug Notices which banned 33 compounds (MOH, 2011b). Despite the bans, the Ministry of Health (MOH) estimated in 2013 that approximately 200–300 psychoactive products were being sold from around 3,000–4,000 retail outlets (MOH, 2014f).

As part of a review of the Misuse of Drugs Act, the New Zealand Law Commission (NZLC), an independent expert body whose task is to review New Zealand laws, recommended establishment of a new regulated market regime for NPS. In their 2011 report, the NZLC concluded that the government could not keep up with the NPS market by banning individual compounds, as producers could easily circumvent legislative controls by instantly substituting newly scheduled drugs with new uncontrolled compounds (NZLC, 2011). The NZLC recommended the development of a new regime requiring sponsors of NPS products to demonstrate their products are safe *before* they are permitted to be sold on the legal market (rather than the government having to prove that the products are unsafe in order to remove products from the market). The NZLC recommended regulation of the market by imposing

controls on the products approved for sale and retailers of these products. The NZLC report became a guiding document for further work on the PSA regime, including MOH regulatory impact statements and the draft legislation, i.e. the PSB.

## **2.2 Issues raised during consultation stage for the PSA**

### **2.2.1. Issues raised in public submissions to the Psychoactive Substances Bill**

The proposed “regulated market regime” outlined in the Psychoactive Substances Bill (PSB) was subject to a public consultation process via written submissions between 9 April 2013 and 1 May 2013. This section contains a summary of postulates raised in written submissions to the PSB. The analytical approach used in the process of analysing submissions to the PSB is explained in Chapter 3 (section 3.2.1.1).

The content analysis included 114 written submissions sourced from the official government website, i.e.: 42 submissions (36.8%) from institutions (institutional submissions) and 72 submissions (63.2%) from private citizens (private submissions).

Most submitters (n=76; 66.7%) supported the regulatory measures proposed in the PSB (40 institutional submissions and 36 private submitters); 25 submitters (21.9%) clearly opposed the measures (2 institutional submissions and 23 private submitters); and 13 submitters (11.4%) (private submitters only) didn’t express a clear opinion about the proposed regulatory regime. Rather than commenting on the proposed content of the PSB, some of these submitters expressed general concern about the harmfulness of NPS to users and communities (n=3; 2.6%), disapproved of the possibility of testing the safety of prospective products on animals (n=2; 1.8%), proposed decriminalisation of cannabis as an alternative measure (n=1; 0.9%), or expressed support for the Bill under the wrongful understanding that it intended to ban all “legal highs” (n=7; 6.1%). Table 1 contains a summary of support for the PSB by submitter type.

#### **2.2.1.1 Reasons behind support and opposition to regulation of the market**

Seventy-six supporting submissions praised the proposed regulatory measures as a “*modern, comprehensive and rational approach*”, stressing the need for regulation of NPS (n=47) and the failure of the traditional drug prohibition measures in the face of the NPS challenge (n=17). Regulation of the market was supported by most submitters from health-related institutions or the health professions (when the individual submitter identified him/herself). The three opposing submitters (PS) from a health background stressed the impossibility of predicting “*the full spectrum of long term adverse health effects and social costs*” (submission no. 20, hospital

scientist) and expressed a preference for “putting the effort into better drug and alcohol rehabilitation and prevention services and programs” (submission no. 90, mental health worker), as well as addressing causes of drug use, such as poverty or poor education (submission no. 56, psychotherapist). The twenty-five opposing submissions largely advocated for a total ban on “legal highs” (n=22), stressing that enough evidence existed that NPS were harmful (n=14), and had negative impacts on local communities (n=12) and youth (n=10). Several submissions (n=3) opposed the proposed measures because they missed the big picture of drug use in NZ. The latter submissions saw the PSA as a “failed opportunity” to modernise drug laws (submission no 45: “This bill is titled: Psychoactive Substances Bill and yet in the opening explanatory notes, it excludes drugs and precursor substances listed in the outdated MODA 1975. Therefore the title is misleading in its intent. Maybe it should be retitled: ‘No change to drug laws’ bill?”), and, in particular, a failed opportunity to regulate cannabis (submission no 80: “Ban all this synthetic stuff, the real stuff is better for you”).

**Table 1: Support and opposition for the PSB by submitter type**

	Overall (n=114)	Institutions (n=42)	Private submitters (n=72)
<b>Support</b>	67% (n=76)	95% (n=40)	50% (n=36)
<b>Oppose</b>	22% (n=25)	5% (n=2)	32%(n=23)
<b>Unclear opinion</b>	11% (n=13)	0	18% (n=13), including 7 claiming to support under the understanding it’s a ban



**2.2.1.2 Recommendations made in public submissions**

Many submitters called for the provisions of the PSB to be viewed through the lens of harm reduction and recommended that a “public health” focus should be added to the aim of the PSB (in its initial version aim was limited to “regulating the availability of NPS”) (n=22). Many submitters also focused on the need to define the “low risk” threshold (n=24) for approval of

products at a level which assures users' safety and yet is achievable (n=14) (submission no. 2: *"The concern is if risk levels are set too high, no products will be allowed; for regulations to work they must be manageable, reasonable and affordable"*). The retail and marketing restrictions proposed by submitters were generally similar or stricter than regulations for the tobacco and alcohol industries, and included proposal to introduce plain packaging (n=4), a total ban on any form of advertising (n=8), R20 or R21 purchase age (n=12), and sale from pharmacies only (n=1). The most commonly recommended public health measure related to the restrictions on the place of sale of approved products (n=33), with 20 submitters calling for the introduction of regime-specific retail licenses, and some submitters suggesting that local communities should have a say in placing further restrictions around the place of sale (n=6). A need to implement a post-approval system for monitoring adverse reactions (n=26) and assure public access to information on approved and non-approved products was widely acknowledged (n=15). Many submitters did not agree with the proposal to punish personal possession of an unapproved product (n=17), and claimed that if this was to be an offence, the onus of proof should be on the police to prove the substance to be illegal (e.g. submission no. 42: *"Innocent until proven guilty is a pillar of our society and should not be easily dismissed"*). Many submitters commented on the broad scope of the proposed definition of "psychoactive substance" (N=13) which *"catches almost everything"* (submission no. 75) and suggested that the regime should be limited to synthetic compounds only and not cover plant products (n=5). Thirty-one submitters raised the issue of testing prospective products on animals, of which 24 called for a total ban on animal testing (10 supporting submissions; 11 opposing submissions and 2 undefined submissions), with some suggesting there are in vitro and in silico alternatives (n=10) or *"plenty of human volunteers"* (submission no 75) to test the products (n=3). Finally, the proposal to allow some existing products to stay on the market under "transitional PSA provisions" was viewed overall as "a sensible approach". However, some submitters were concerned about the possible duration of temporary measures (n=12), calling for a speeding up of the regulatory process (n=6), while others thought that the sale of products should be discontinued until the full regulatory regime was operational (n=6).

### **2.2.2 Issues raised in parliamentary debates**

The three readings of the proposed Psychoactive Substances Bill (PSB) took place in Parliament on 9 April 2013, 2 July 2013 and 11 July 2013. This section contains a summary of key issues raised during the parliamentary debates. Transcripts of debates were sourced from the official

government database (parliament.govt.nz). The analytical approach used to analyse transcripts of the parliamentary debates on the PSB is explained in Chapter 3 (section 3.2.3).

Overall, the governing National Party and its coalition MPs stressed the prohibitive measures included in the PSB and the need for high safety standards and stringent regulation (exemplary quotes from the government party politicians: *“I make no apology for the fact that we will set a deliberately high bar, and that those who want to go through the process will pay an exorbitant fee”*; *“I hope that for those who are producing the K2s and the synthetic drugs out there, and experimenting on young people, that this sends them out of business”*). On the other hand, the opposition largely viewed the PSB as a *“missed opportunity for a comprehensive overhaul of MODA”* and focused on procedural shortcuts in the process of adopting the law. Table 2 summarises major themes raised by the opposition and the government during parliamentary debates.

**Table 2: Themes identified in the analysis of parliamentary readings on the PSB**

Opposing views:		Points of agreement:
Opposition	Government and coalition	
<ul style="list-style-type: none"> <li>Views PSB as a missed opportunity for a comprehensive overhaul of the Misuse of Drugs Act (MODA)</li> <li>Criticises the government for rushing the procedures, in particular cutting down the standard Select Committee stage from 6 to 2 months; criticises government for not paying enough attention to the animal testing issue</li> <li>Largely opposes punishing personal possession of unapproved NPS as it has not been proven of benefit to users under MODA and will not be enforceable</li> <li>Green Party calls for a total ban on animal testing claiming that alternatives exist and are more reliable than animal models</li> </ul>	<ul style="list-style-type: none"> <li>Stress that the PSB is only about NPS and will not be extended to regulate cannabis</li> <li>Stress prohibitive measures of the PSB, high standards testing regime and possible obstacles for the industry to get a product approved (high fees and safety standards)</li> <li>Stress that personal possession is punished in order to facilitate health and social intervention, and not to go down the “criminal pathway”.</li> <li>Rationalise why animal testing is not banned in the PSB: (1) consensus has been reached by allowing animal tests <i>only</i> if there is no alternative; (2) scientific advice that some animal tests are needed in order for the regime to work; (3) testing on animal prevents “testing on people”</li> </ul>	<ul style="list-style-type: none"> <li>Current system of Temporary Class Drug Notices (TCDN) doesn’t work</li> <li>“Total ban” on these products is not possible due to variety of substances on the market</li> <li>Agree on the urgency of this law as TCDNs are about to expire</li> <li>Agree that the law needs to be reviewed after 5 years and further measures need to be considered then, including excise tax</li> </ul>

## 2.3 Regulatory mechanisms under the PSA

The PSA was passed in July 2013 with nearly unanimous cross-party support in Parliament (119 in favour and 1 vote against the legislation) (New Zealand Parliament, 2013b). It established the world's first ever regulated legal market for NPS (Wilkins, 2014a). The objective of the PSA, as defined in s. 3 of the Act, is to “regulate the availability of psychoactive substances in New Zealand to protect the health of, and minimise harm to, individuals who use psychoactive substances”.

Under the PSA regime, product sponsors can get a government approval to legally import, manufacture and sell psychoactive products containing NPS, provided they prove that the products are “low risk”. The importation, manufacture, supply and possession of any other “unapproved” NPS is prohibited by default (Rychert & Wilkins, 2016b).

Requirements for testing the safety of psychoactive products resemble the pre-market approval regime for medicines and are modelled on pharmaceutical standards developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This means that scientific evidence from a series of toxicology and clinical trials is required for each product application, and should cover aspects of the product's safety such as pharmacology, general toxicity, assessment of pharmacokinetics, metabolism and potential to cause addiction (PSRA, 2014a). The approval is granted for each separate *product formulation* (not *substance*), and thus the strength of the product cannot be modified once approval is granted. The Ministry of Health estimated the cost of testing as likely to be 1–2 million NZD per product (MOH, 2012). The product application fee is set at 175,000 NZD per product (MOH, 2014c). While this might seem like a lot of money, returns from the market are likely to compensate the initial expenses (Wilkins, 2014d). The estimated annual retail sale from a regulated SC market during the “interim phase” of the PSA implementation reached 140 million NZD (MOH, 2014f).

The retail framework for the regime is modelled on regulations for alcohol and tobacco, with approved products allowed to be legally sold only from specialised licensed retail outlets. No food or alcohol can be sold from the same premises and the PSA explicitly bans the sale of products from supermarkets, petrol stations, local convenience stores or alcohol retail outlets. Retail sales are only allowed to customers 18 years of age and over (which matches the legal drinking age limit in New Zealand). Following postulates raised in the public submissions process, the PSA allows local councils to place further restrictions on location of licensed retailers, including minimum distance from “sensitive sites” such as schools, sports fields or churches.

The advertising of approved NPS products is limited to the point-of-sale only (i.e. no advertising in television, radio, or newspapers) and must be limited to objective information about the product, such as active ingredients and the price. The PSA specifically prohibits advertising in a form which conveys a message that an approved product is “safe”. While online sale of products is allowed, it can only be done through websites established specifically for this purpose (but not other internet platforms, including social media websites). Packaging for NPS products must include a list of ingredients, health warnings, contact details of the manufacturer and the telephone number of the National Poisons Centre (New Zealand Parliament, 2013a).

The Psychoactive Substances Regulatory Authority (PSRA), a new government agency established within the Ministry of Health (MOH), is tasked with overseeing implementation of the PSA. The PSRA has the ability to revoke any product approval if, after introducing the product to the market, reports about adverse effects emerge and the product is no longer considered to be “low risk”.

## **2.4 The interim regulated market under the PSA**

When the PSA was passed in July 2013, much of the regulatory framework to make the new regime workable had not yet been developed, including the required safety testing standards or detailed rules for online sale of approved products. While these regulations were being developed by the PSRA, the “interim regime” was established, allowing a limited number of “legal high” products available on the market before the passage of the PSA to continue to be sold subject to new retail and advertising restrictions established under the PSA (Schedule 1 PSA as enacted). This was deemed necessary to avoid the creation of a black market which could have emerged if all “legal high” products had been banned as “unapproved” NPS in the wake of passage of the PSA (New Zealand Parliament, 2013b). The transitional provisions were intended to last until all regulations for the PSA regime were finalised (s. 6 and 9, Schedule 1, PSA as enacted), after which time any product allowed on the market would need to pass the required safety tests to prove its consumption poses no more than a “low risk” to consumers.

### **2.4.1 Managing products approved on the interim market**

Forty-seven products received interim approvals under the interim regime, including 40 SC smoking blends (Wilkins, 2014b). The interim approved products did not pass any safety tests but were deemed to be “low risk” as they had been on the market for at least three months before the PSA and there were no significant adverse event notifications against them. The PSRA

was tasked with monitoring the safety of interim approved products allowed on the market and had the power to revoke interim approval for any product if information about adverse events emerged. There were three designated sources of data: (i) calls from members of the public to the National Poisons Centre (NPC) and Drug and Alcohol Helpline; (ii) reports sent by medical professionals to the Pharmacovigilance Centre (CARM) and reports made by a subset of hospital emergency units; and (iii) notifications from product manufacturers who were legally obliged to report adverse incidents from their products (MOH, 2013b).

Data collected by the National Poisons Centre showed an increased number of SC-related calls from the general public following the establishment of the interim regime. This increase may have been largely due to the requirement for interim approved products to display the NPC telephone number on product packaging.

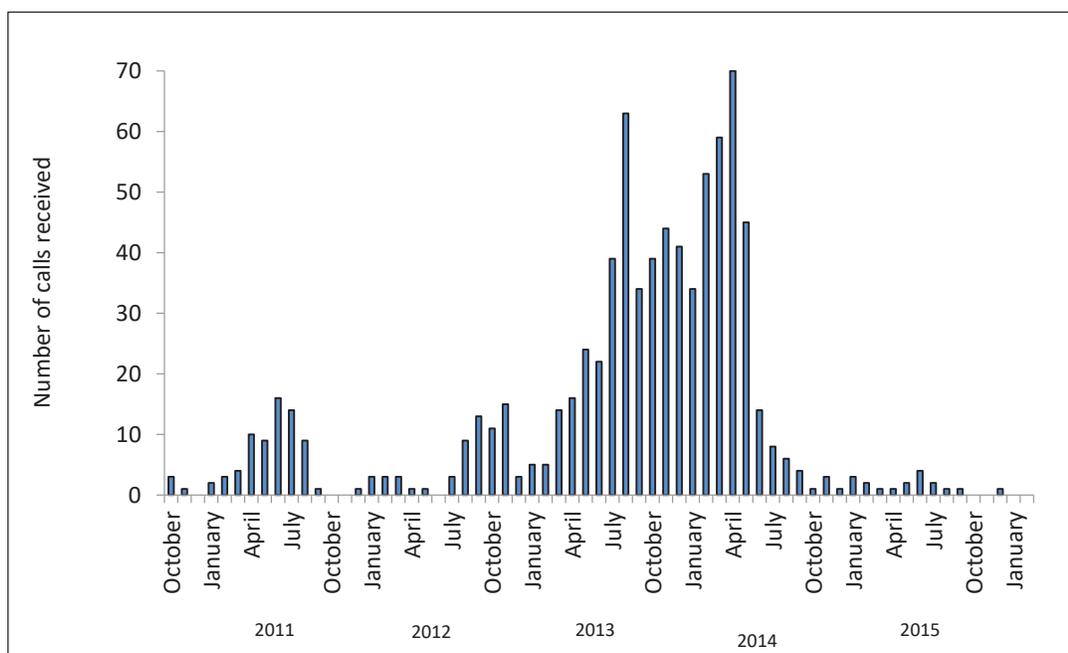


Figure 5: SC-related calls received by the National Poisons Centre (October 2010 – February 2016)

Data compiled by Leo Shep, PhD. Source: National Poisons Centre Update March 2016.

Eleven interim product approvals were revoked by the PSRA due to harms reported during the interim regime: five in January 2014 (Wilkins, 2014b) and six in May 2014 (MOH, 2014b). Table 3 presents the names and active compounds in the products withdrawn during the interim regime and the composition of products which remained on the regulated legal market until the end of the interim regime.

**Table 3: Interim approved products withdrawn during the interim regime and products which remained on the interim market until PSAA (by active ingredient and declared concentration).** Compiled from data archived on PSRA website.

Active ingredient	Products withdrawn during the interim regime		Products which remained on the interim PSA market until the ending of the interim regime	
AB-FUBINACA	Apocalypse	100 mg/gm	Tai High Bubble Berry	45 mg/gm
	Outbreak	100 mg/gm	Master Kush	45 mg/gm
	Lemon Grass	40 mg/gm	Illusion Peak	40 mg/gm
	Blueberry Crush	35 mg/gm	Choco Haze	40 mg/gm
			Amsterdam Havana Special	35 mg/gm
PB22-5F	AK47	60 mg/gm	Tai High Purple Passion	60 mg/gm
	WTF	24.3 mg/gm	XT	50 mg/gm
			Illusion Connoisseur	45 mg/gm
			Illusion Massif	40 mg/gm
			DC-3 Purple	40 mg/gm
			Puff Southern Lights	35 mg/gm
mix of AB-FUBINACA and PB22-5F			Kush Pink	120 mg/gm
			Mind Trip	70 mg/gm
PB22	Anarchy	90 mg/gm	Red X	50 mg/gm
	Voodoo	90 mg/gm	Tai High Black	50 mg/gm
	Karma	90 mg/gm	Radiation	40 mg/gm
CL-2201	Northern Lights Promo	50 mg/gm	Tai High Afghan Kush	60 mg/gm
			Amsterdam Long Island Tea	50 mg/gm
			Jungle Juice	50 mg/gm
			Illusion Colossus	45 mg/gm
			Puff Super Strength	40 mg/gm
CP-55,244	White Rhino	50 mg/gm		
Various amino acids, kava, caffeine, vitamin B mixes			A range of products: Dr Feelgood, Pepe, Nirvana, POW, PURE-GOE	Information not available
			Stargate (tri-xanthine mix)	880 mg per tablet
SGT-24			SGT-24	5 mg/gm
			Giggle	5 mg/gm
			Diablo	5 mg/gm
SGT-42			4:20 pill	1 mg/550 mg
AB-005			Ziggy	90 mg/gm
AM-2201			B-52 Berry Bomb	41 mg/gm
5F-ADBICA			Haze	26 mg/gm
			Northern Lights Black	20 mg/gm

## 2.4.2 Interim licensed retailers and community protests

One-hundred and fifty-two specialised retailers were licensed to sell approved “legal highs” on the interim market. This constituted a 95% reduction in the number of shops selling NPS

compared to the pre-PSA period when an estimated 4,000 unlicensed retailers sold NPS products. Thirteen of the interim licensed retailers were closed during the interim regime due to non-compliance with the retail restrictions established under the PSA (such as the ban on selling alcohol from the same premises).

Anecdotal evidence from the New Zealand media suggests significant community opposition to the interim licensed shops had built up towards the end of the interim regime. Large numbers of customers queuing in front of the stores featured in some media stories (e.g. 3 News online, 2014; Smallman & Leaman, 2014). Some media portrayed the customers in a negative way, reporting that stores “attracted criminals and young people who were begging or prostituting themselves to raise money for the drugs” (e.g. Davison, 2014). Community concerns with the interim licensed retailers led to public protests against the shops, which became a major theme in media reporting during the interim regime (e.g. MacLean, 2013; Norton, 2014). The media linked public protests to social disruption around retail outlets and public opposition to SC products being approved for sale during the interim regime (e.g. Collins, 2014; Rilkoff, 2014).

#### **2.4.3 The Psychoactive Substances Amendment Act and ending of the interim regime**

In May 2014, the interim regime was abruptly ended by the parliamentary amendment to the PSA (Psychoactive Substances Amendment Act 2014, PSAA). The PSAA was passed under urgency and revoked all remaining interim product approvals and over 130 interim retail licenses. The decision to end the interim regime was officially attributed to the ongoing “harms evidenced with the products” on the interim market (MOH, 2014f), and ongoing issues with social disruption around licensed retail outlets (Wilkins, 2014c). While the amendment ended the interim regime, the work on developing PSA regulations continued and in November 2014 the regime was opened to receive applications under the full testing framework requiring the evidence of “low risk” from clinical trials.

The PSAA also introduced a ban on the use of animals for the purpose of testing the safety of products under the full PSA testing framework. This came after a wave of protests against testing psychoactive products on animals. The ban on animal testing posed serious questions about the feasibility of providing evidence of “low risk” by product sponsors who wish to apply for product approval under the full PSA testing framework (Bell, 2015; Rychert & Wilkins, 2015b; Schep, Gee, Tingle, Galea, & Newcombe, 2014). The PSRA has gone so far as to state that “it is unlikely that a product can be shown to pose no more than a low risk of harm without the use of animal testing”; suggesting the animal testing ban made the PSA unworkable (PSRA, 2014a).

## 2.5 Existing evidence and evaluations of the PSA

The number of authorities around the world expressing interest in monitoring progress with the implementation of the PSA (Commission on Narcotic Drugs, 2016; EMCDDA, 2015e; UK NPS Review Expert Panel, 2014; UNODC, 2013a) indicates the need to explore challenges experienced during the interim regime and investigate the reasons for its abrupt ending. Such an investigation would inform future implementation of the PSA and identify learnings for other countries. To date, only a handful of authors have attempted to reflect on the PSA regulatory framework and the challenges experienced during the PSA implementation.

Existing critical analyses have focused on the envisioned full PSA regime. Wilkins (2014a) posed a number of theoretical questions about the future testing framework, including the limitations of standard medical clinical trials in assessing the risks of recreational products due to hedonistic patterns of recreational drug use, including polydrug and binge use. Ethical questions have also been raised regarding the use of standard clinical trials to assess the safety of NPS products, with some authors suggesting that recreational products have potential harms but offer “no clear benefit” (Von Diemen, 2014). Conceptual difficulties with defining the level of “low risk” (i.e. the threshold for product approval under the PSA) have also been raised in academic debate (Reuter & Pardo, 2017; Wilkins, 2014a), with some authors going so far as to criticise the New Zealand government for failing to provide an explicit definition of the level of risk acceptable for regulatory approval of recreational products (Reuter & Pardo, 2017).

In his critical analysis, Wilkins (2014a) also pointed to other issues which may undermine the effectiveness of the PSA regime in the future, including uncertainties about public health outcomes and challenges in suppressing the black market for NPS because of the physical similarity between legally approved products and illegal “unapproved” products containing NPS. Some authors have suggested that illegal competition to the legal regulated market under the PSA, as well as the costs of running the business legally, may undermine operators’ willingness to engage with the regulated market (Bretteville-Jensen, 2014; Hughes & Griffiths, 2014; Von Diemen, 2014). Finally, scepticism has been expressed about whether “low risk” approved products will be attractive enough to customers to draw demand away from the potentially stronger black market NPS compounds (Hughes & Griffiths, 2014).

The first evaluation of the regulatory framework developed to manage the interim market was undertaken six months into the interim regime. Wilkins (2014b) described and analysed the framework developed by the PSRA to assess the safety of products allowed on the market. He cautiously concluded that the framework design was “appropriate”, but the effectiveness of

monitoring products' safety in practice "will depend on the quality of the data available on adverse cases" (Wilkins, 2014b). The paper also described enforcement powers given to the PSRA, the police, and public health officers to monitor the NPS market, but no assessment was provided of how they were being applied in practice during the interim regime. For the first time the problem of "community concern" with the interim regime was raised in the context of the PSA implementation, and the public's frustration was attributed to the "perception that the PSA did not change a great deal" (Wilkins, 2014b).

After the ending of the interim regime, a number of studies retrospectively investigated health impacts of the new regulated market approach. They identified health problems and issues of dependency related to SC products used during the interim PSA regime (Glue, Courts, Gray, & Patterson, 2016; Glue, Courts, MacDonald, Gale, & Mason, 2015; Macfarlane & Christie, 2015; Wilkins, Prasad, Wong, Graydon-Guy, & Rychert, 2016). A retrospective audit of hospital presentations found a temporary reduction in hospital presentations due to SC use following establishment of the interim regime, which was linked to reduced availability of NPS during the interim regime compared to the pre-PSA unregulated market (Glue et al., 2016). The number of hospital presentations, however, increased over time and further reduction in hospital presentations was only seen after the ending of the interim regime (Glue et al., 2016). Similarly, drug use monitoring studies found a decrease in prevalence of SC use following the ending of the interim regime. The Illicit Drug Monitoring System (IDMS), conducted yearly by the SHORE & Whāriki Research Centre, found that the current use of SC (i.e. use in the last 6 months) dropped between 2013 and 2014: from 30% to 23% among methamphetamine users, from 22% to 6% among ecstasy users and from 21% to 10% among injecting drug users (Wilkins, Prasad, Wong, & Rychert, 2015). There is no data on SC use in general population available in New Zealand.

## **2.6 Knowledge gaps and PhD research focus**

As discussed in section 2.5, existing research and analyses of the PSA consist mostly of retrospective health impact assessments (applying quantitative methodologies) and prospective critical theoretical evaluations of the envisioned full PSA framework. No research had been completed to date on the organisational, social and regulatory aspects of managing the PSA regime in practice.

The abrupt ending of the interim PSA regime raised a number of questions relating to the issues and challenges experienced during the interim phase of the PSA implementation. These include:

(1) the effectiveness of the regulatory systems in monitoring the safety of approved products, identifying products causing harms and withdrawing interim approvals if concerns arise; (2) the effectiveness of monitoring regulatory compliance of the interim licensed retailers; (3) the reasons for “community concerns” with the new regime and how communication of the policy was managed, and (4) issues with commercialisation of the market, including the marketing and political strategies employed by the legal high industry in response to regulation of the market.

Existing critical evaluations of the PSA content have focused on the envisioned product approval framework under the full PSA regime, and the challenges of defining the concept of “low risk”. To date, however, other PSA provisions have turned out to be particularly problematic during the implementation process. First, the prohibition on the use of animals for the purpose of testing the safety of products has raised questions about the future of the regime. Second, the concept “psychoactivity” has been heavily criticised in the academic debate when used in laws controlling NPS.

One of the aims of the PSA is to separate the approved market from the unapproved market for NPS. Wilkins (2014a) hypothesised that, as a consequence of market regulations under the PSA, people would be likely to perceive government-approved “legal highs” as safer and more legitimate than NPS products which are unapproved and black market drugs. This hypothesis, however, has not been tested to date. This is significant as some authors have suggested that changes in prevalence of use of recreational drugs are influenced not only by their availability, but also by social perceptions about acceptability and health risks.

This PhD will explore the above-mentioned issues and thus contribute to an increased understanding of why the interim regime was ended in May 2014, and what challenges may be experienced in the future implementation of PSA under the full regime. It will add to the current literature by:

- (1) focusing critical analysis of the PSA content on legislative provisions which turned out to be particularly problematic during the implementation process, i.e. the animal testing ban and the definition of psychoactivity;
- (2) retrospectively investigating issues with management of the interim market related to approving and monitoring the safety of interim approved products;
- (3) exploring challenges with management of the interim market related to enforcement of regulations around retailers and the communication of the policy to the public;

- (4) investigating how the legal high industry (LHI) viewed market regulation and responded to new legal controls under the PSA and the changes in the market;
- (5) exploring the impact of the government approval for psychoactive products on perceptions about their health risks and the social acceptability of using “legal high” products.

## 2.7 Research aims and objectives

The overall aim of this thesis is to investigate and critically analyse the PSA and its implementation process in order to better understand issues and challenges with establishing and monitoring a regulated legal market for NPS. Accordingly, the thesis investigates, analyses and critiques both policy content (i.e. legislative provisions of the PSA) and policy processes (i.e. the process of adopting and implementing the PSA). It also investigates social impacts of the PSA, including the impact of government approval for recreational “psychoactive products” on perceptions about the health risk and social acceptability of using “legal highs”.

The specific objectives of this thesis and the rationales for respective research papers are explained in Table 4.

**Table 4: Objectives of the PhD and rationales for research papers**

	Research objectives:	Rationale:	
1.	to analyse how the legal definition of “psychoactive substance” is operationalised in practice	The problem of defining what “psychoactive” substances should be covered by legislation aimed at controlling NPS is central to the current debate about innovative policy responses to “legal highs”. The concept of “psychoactivity” in particular has received criticism when used in legislation. I analyse the PSA definition of psychoactivity and the potential overlaps with other laws covering substances with psychoactive effects (e.g. medicines, dietary supplements) to better understand challenges in enforcement and potential solutions.	Chapter 4
2.	to explore issues with the implementation of regulatory systems to monitor the safety of products during the interim regime	The decision to end the interim regime was officially explained by the ongoing reports of harms evidenced from the interim approved products. The regulatory framework to monitor the safety of products allowed on the market has previously been described (Wilkins, 2014b), but no assessment about how it worked in practice has been provided. I explore issues related to the development and implementation of systems for ongoing monitoring of product safety during the interim regime.	Chapter 5

3.	to explore challenges in relation to regulating the retail environment and communication about the PSA to the public during the interim regime	Organisational, social and regulatory aspects of managing the “regulated market” regime under the PSA have not been investigated to date. Challenges with enforcement of regulations around retailers and communication of the policy to the public are explored in interviews with information-rich key informants to provide a better understanding of issues with implementation of a “regulated market” approach to NPS.	Chapter 6
4.	to explore how the “legal high” industry (LHI) viewed and responded to the regulation of the market under the PSA	Passage of the PSA legitimised a new commercial industry in the legal recreational products sector, which had been previously limited to alcohol and tobacco. While extensive research has been completed on business strategies employed by alcohol and tobacco, little is known about the new “legal high” industry (LHI). Better understanding of LHI motivations and business strategies will inform effective implementation strategies of the PSA.	Chapter 7
5.	to examine the impact of government approval of recreational psychoactive products on perceptions of the safety and social acceptability of using “legal highs”	One of the aims of the PSA is to separate the legal market for approved NPS products from the black market. It has been hypothesised that, as a consequence of market regulation, people are likely to perceive government-approved products as safer and more socially acceptable than unapproved NPS and illegal drugs. I test this hypothesis by investigating perceptions about health risk and social acceptability for government-approved “legal highs” during the interim regime relative to other drugs.	Chapter 8
6.	to investigate options to move the “regulated market” regime forward despite the ban on animal testing	The amendment to the PSA in May 2014 imposed a ban on the use of animals for the purpose of testing the safety of psychoactive products for regulatory approval. The PSRA suggested this may have made the new regime unworkable. I investigate strategic options to circumvent the animal testing ban and move the regime forward.	Chapter 9

## 2.8 Structure of the thesis

The thesis is principally comprised of six research papers that work together to increase understanding of issues experienced with regulating NPS in New Zealand under the PSA.

Chapter 3 outlines the theoretical framework for Public Health Law Research and research methods applied in the papers to investigate the PSA and its implementation. Each paper investigates a different aspect of the regime, according to the research objective outlined above in section 2.7. The research results chapters (4–9) begin with the analysis of how the definition of “psychoactivity” is operationalised in the New Zealand legal context (Chapter 4), thus providing an overall background to the legislative environment in which the PSA operates. The thesis then goes on to explore challenges experienced during the interim regime, including issues with monitoring the safety of interim approved products (Chapter 5) and establishing an effective retail environment and public communication of the new policy during the interim regime (chapter 6), and the challenges related to commercialisation of the market (Chapter 7). Following this, social impacts of the regulated legal market are explored in more depth as I investigate whether government approval of “legal highs” influenced social perceptions about health risks and social acceptability of using the products (Chapter 8). The results section of the PhD concludes with investigation of the future scenarios for the regime in the face of the ban on animal testing imposed by the PSAA (Chapter 8). The order of the research papers included in results chapters does not reflect chronology of publications.

Relevant literature is summarised in the introduction to each chapter to provide context for the analysis and argument that follow. Only studies published at the time the original research paper was submitted are included in the literature reviews. Some paragraphs are similar through the thesis due to the format of “PhD by publication”. Research papers are linked by brief “linking sections”.

The final chapter synthesises findings from the research and discusses the contribution of this thesis to the drug policy literature. The implications for drug policy are discussed in the context of the NPS challenge and the emerging drug policy reforms witnessed recently in the US, Canada and Uruguay with the regulation of cannabis for recreational use. Finally, research limitations and strengths are discussed and directions for the future research are proposed.



## Chapter 3: Theoretical framework and methodology

### 3.1 Theoretical framework

The theoretical framework applied in this thesis was developed for and by public health law researchers (Figure 6). It theorises how law, lawmaking processes and enforcement practices can influence health outcomes and hence are worthy of study from a public health perspective (Burriss et al., 2010; Komro, O'Mara, & Wagenaar, 2013). It proposes that the law, i.e. how it is designed (*law in books*) and implemented (*law in action*), influences public health outcomes through mediating factors such as changes in environments (e.g. physical availability of NPS, social norms around NPS use) and changes in behaviours (e.g. willingness to engage in sanctioned behaviour; substitution of other psychoactive drugs with NPS). The authors of the model imply that any of the elements along this pathway, i.e. content of laws, process of adopting the law, implementation of the law and changes in regulatory and social environments may impact on public health outcomes and therefore warrant scientific inquiry (Burriss et al., 2010).

This thesis applies the Public Health Law Research (PHLR) framework to analyse the legal framework for the new regulatory regime for NPS established by the PSA, the implementation process for the PSA and its impact on some mediating factors (namely, perceptions of safety and social acceptability of approved NPS products).

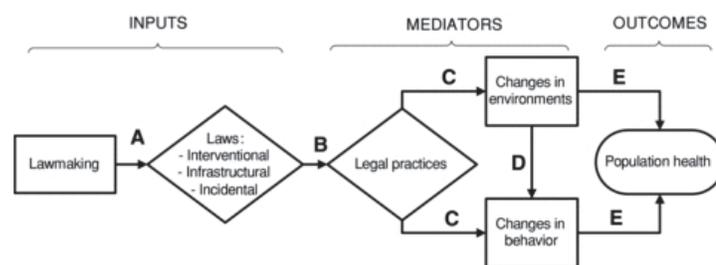


Figure 6: Logic model of the Public Health Law Research (Burriss et al., 2010)

### 3.2 A note on epistemological position

While the authors of the theoretical framework outlined above do not link their model to any specific philosophical paradigm, they argue that "empiricism" is "both a methodology and a

philosophy” that underpins their understanding of how public health law research adds to the production of knowledge (Burris et al., 2010). The emphasis on empirical “evidence derived from rigorous research” (Burris et al., 2010) situates them in the positivist epistemology movement and in objective ontology philosophy.

In this thesis, I maintain an objective understanding of reality and a “realist approach” to studying health and law mechanisms. However, my epistemological position deviates from traditional positivism in that I accept a degree of *interpretivism* or *social constructivism* in our *understanding* of reality. Thus, a critical realist social science philosophy is adopted in this thesis.

“Critical realism”, the most prominent manifestation of realism in the social sciences, was first proposed by Roy Bhaskar (Bhaskar, 1989, 1998 [1978], 2008 [1975]) and has been developed and modified by numerous social scientists, philosophers and legal scholars (Archer, Bhaskar, Collier, Lawson, & Norrie, 1998; D. Campbell, 1988; Sayer, 2000). In essence, critical realists maintain ontological realism (i.e. the existence of reality independent from our perceptions) while accepting a form of epistemological constructivism (i.e. that our understanding of the topics is influenced by our perspective) (Maxwell, 2012).

The “constructivist” element of social science philosophy is evidenced in my attempt to gather diverse views on issues with the PSA implementation by interviewing stakeholders from different backgrounds. The use of inductive reasoning in the process of thematic analysis also reflects my adoption of epistemological constructivism.

### **3.3 Mixed methods approach**

A range of legal and policy analysis approaches to data collection and analysis were employed to critically evaluate the PSA and its implementation process.

First, secondary data sources were identified by searching official government databases (keywords: “Psychoactive Substances (Amendment) Act”, “Psychoactive Substances (Amendment) Bill”). The government databases searched included the repository of current NZ laws (legislation.govt.nz), repository of regulatory impact statements (treasury.govt.nz); repository of parliamentary debates and public submissions (parliament.govt.nz); archive of public communications from the government (beehive.govt.nz); police apprehension statistics (stats.govt.nz) and court decisions (justice.govt.nz). These secondary sources informed my initial understanding of issues with the PSA, and helped specify research questions and identify relevant primary data sources.

Second, interviews were conducted with key informants (KI) involved and/or affected by the implementation of the PSA regime. Key informants were identified during the review of secondary data, primarily analysis of public submissions to the Bill, and through KI referrals. The KI interviews generated the primary qualitative data.

Third, relevant questionnaire items were added to an annual survey of police arrestees to further investigate impacts of the PSA. This was enabled by the author's involvement in the work of the Drugs Team at the SHORE & Whāriki Research Centre. Each year, SHORE conducts two drug use monitoring studies: the Illicit Drug Monitoring System (IDMS), where around 300 frequent drug users are surveyed about their drugs use, and the New Zealand Arrestee Drug Use Monitoring study (NZ-ADUM), where approximately 800 police arrestees are surveyed about their drug use. NZ-ADUM was considered more appropriate to investigate perceptions of the health risk and social acceptability of the government-approved NPS products as this larger sample provided opportunities to examine perceptions among different sub-groups of drug users and other demographic groups (e.g. younger and older, females and males), and the timing of the survey fitted better with the operation of the regime. Data gathered through NZ-ADUM constitute the primary quantitative data used in this thesis.

The data analysis included: (1) content analysis of laws, parliamentary debates, public submissions and other policy documents; (2) thematic analysis of interviews with key informants, including politicians, government officials, industry actors, health professionals, NGOs and drug services workers; and (3) statistical analysis of data from an annual survey of police arrestees (i.e. data on perceived health risks and social acceptability of approved "legal highs"). The progression of research process is illustrated in Figure 7 (page 40).

The mixed methods approach used in this PhD study prioritises a qualitative research design, i.e. the quantitative data and its analysis provide a supporting role in a larger "qualitative study". Accordingly, a "concurrent embedded strategy" of mixed methods (Creswell, 2009) is adopted, where the qualitative method is primary and guides the project, and the quantitative data provides a supporting role and is "embedded" within the predominant method. In this PhD, the "secondary" quantitative method is used to address a specific research question, i.e. it investigates social perceptions about risks and acceptability of approved "recreational products", while the qualitative data explored wider social, regulatory and legal challenges experienced during PSA implementation. The qualitative approach was prioritised as it provided a means to get deeper and richer understanding of the issues identified.

Table 5 outlines how the methods used in this PhD research fit within the typology of Public Health Law Studies (Tremper, Thomas, & Wagenaar, 2010). The methods employed in this Thesis are underlined. The remaining section of this chapter explains methods used to collect and analyse data in more depth.

**Table 5: Typology of Public Health Law Studies (Burris et al., 2010) and their relevance to this thesis**

Study Type	Purpose	Available methods, as proposed by Burris et al. (2010) (methods used in this PhD study underlined)	This PhD
Policymaking studies	To identify factors influencing the likelihood that public health laws will be adopted, the nature of laws adopted, and the process through which they are adopted	<ul style="list-style-type: none"> <li>• <u>Key informant interviews</u> • <u>Content analysis of transcripts, rule-making notices, memos, and other policy materials</u> • Surveys of policymakers • Multivariate regression</li> </ul>	<ul style="list-style-type: none"> <li>• Chapter 2, s. 2.3 analyses elements of public consultation process (i.e. written submissions) and parliamentary procedures</li> <li>• Chapter 6 contains a discussion about how the process of adopting the PSA may have influenced challenges experienced during the interim PSA regime</li> </ul>
Mapping studies	To analyse the state of the law or the legal terrain and the application of laws surrounding a particular public health topic	<ul style="list-style-type: none"> <li>• <u>Content analysis of statutes, administrative regulations, and formal policy statements</u> • <u>Key informant interviews</u> • Surveys of state and local policymakers</li> </ul>	<ul style="list-style-type: none"> <li>• Chapter 4 investigates the relationship between the PSA and other current laws, including medicines and dietary supplement regulations</li> <li>• Chapter 9 investigates legal options to move the regime forward despite the ban on animal testing imposed by the PSAA</li> </ul>
Implementation studies	To examine how and to what extent the “law on the books” is implemented and enforced through legal practices	<ul style="list-style-type: none"> <li>• <u>Content analysis of administrative agency documents, including public communications</u> • <u>Key informant interviews</u> • <u>Examination of business records of regulated entities</u> • Direct observation of enforcement actions • Surveys of regulators, regulated entities, and the public</li> </ul>	<ul style="list-style-type: none"> <li>• Chapter 5 investigates implementation of regulations to monitor the safety of interim approved products</li> <li>• Chapter 6 explores issues with enforcement of regulations around retailers and communication of the policy to the public during the interim regime</li> <li>• Chapter 7 analyses how the legal high industry viewed and responded to market regulation</li> </ul>
Intervention studies	To assess the effect of a legal intervention on health outcomes or <u>mediating factors</u> that influence health outcomes	<ul style="list-style-type: none"> <li>• Descriptive analysis of outcomes data • <u>Multivariate regression</u> • Case/control designs • Controlled experiments • Simulations • <u>Surveys of persons targeted by the law</u></li> </ul>	<ul style="list-style-type: none"> <li>• Chapter 8 explores whether government approval of psychoactive products is associated with reduced risk perceptions and increased social acceptability for “legal highs”</li> </ul>

### **3.3.1 Document analysis**

A range of documentary sources were accessed and analysed for this thesis, including legislation, public policy documents, administrative and judicial decisions and “legal high” industry documents. As explained above, relevant documents were identified by searching official government databases including: the repository of current NZ laws (legislation.govt.nz), repository of regulatory impact statements (treasury.govt.nz); repository of parliamentary debates and public submissions (parliament.govt.nz); archive of public communications from the government (beehive.govt.nz); police apprehension statistics (stats.govt.nz) and court decisions (justice.govt.nz). Legal high industry documents were accessed through Google searches, including the internet archive website web.archive.org.

The specific documents read and analysed included: (1) PSA legislation and administrative regulations, i.e. the PSA, the PSAA, Psychoactive Substances Regulations 2014 and Psychoactive Substances Product Approval Guidelines; (2) official policy documents, i.e. parliamentary readings of the PSA and the PSAA, MOH regulatory impact statements, public submissions to the Psychoactive Substances Bill and the Psychoactive Substances Amendment Bill, the report of the Health Select Committee, and formal policy statements released by the government; (3) decisions issued by relevant government agencies such as the Ministry of Health (i.e. product approvals and retail licences granted for the interim PSA regime and later withdrawn) and courts of New Zealand (i.e. judicial decisions); (4) regulatory instruments issued by local governments (i.e. Local Approved Products Policies (LAPP) developed in Auckland and Hamilton); (5) related legislation, e.g. Misuse of Drugs Act, Medicines Act, Dietary Supplements Regulations and Food Act; (6) documents publicly released by the “legal high” industry including self-regulation documents, media statements and public submissions.

#### ***3.3.1.1. Content analysis of written submissions to the PSA***

Written submissions to the Psychoactive Substances Bill were sourced from the official government website (parliament.govt.nz) ("Submissions to the Psychoactive Substances Bill 2013,")("Submissions to the Psychoactive Substances Bill 2013,"). The analysis included 114 written submissions (15 documents with exactly the same content as other submissions were excluded from the analysis). Submissions were analysed systematically using a content analysis approach (Joffe & Yardley, 2004). Submissions were read and categorised into three mutually exclusive groups reflecting their support for the PSA regime (i.e. expressed support, opposed, or undefined), and the content of submissions then coded for: (1) reasons for the position (if mentioned); and (2) specific recommendations regarding the PSA regime made in submissions

(if mentioned). Initial codes were identified during the first reading of submissions and then updated and finalised as new reasons for support and recommendations were identified during the second reading of submissions. Following this, submissions were read a third time to ensure all submissions had been coded for all identified codes. The principal findings from this content analysis are outlined in Chapter 2. This analysis constituted part of formative research for the PhD and helped to identify key issues with the PSA to be investigated in one-on-one interviews with key informants.

### ***3.3.1.2 Thematic analysis of parliamentary debates***

Parliamentary debates on the Psychoactive Substances Bill (New Zealand Parliament, 2013b) were sourced from the official government database ([parliament.govt.nz](http://parliament.govt.nz)) and analysed systematically using a pragmatic approach to thematic analysis (Aronson, 1995). The procedure for thematic analysis included coding all of the dataset (i.e. transcripts of parliamentary debates) for patterns (i.e. specific issues raised by each speaker during parliamentary debates on the Bill) and combining patterns into themes (Aronson, 1995). For example, when the reasons behind criticism or support for a particular provision of the Bill were explained or elaborated on by a parliamentarian, they were initially all coded as detailed “patterns” and then relevant codes were combined into larger “themes”. Finally, identified themes were categorised into points of agreement and disagreement raised by the government and the opposition. To this end, the political affiliation of all parliamentarians speaking during the debates was identified. The summary of findings from this pragmatic thematic analysis is also presented in the previous chapter. This analysis constituted part of formative research for this PhD study and helped identify issues to be raised in one-on-one interviews with key informants.

### ***3.3.1.3 Legal analysis of the PSA and other legal sources***

Legal analysis was undertaken of specific PSA provisions which proved to be particularly controversial during the implementation of the law. This included the legal definition of “psychoactive substance” (s. 8, 9(1) PSA) and the prohibition on the use of animal testing for the purpose of assessing the safety of products (s. 12(1) PSA). The analysis aimed to investigate how the definition of “psychoactive substance” is operationalised in practice (Chapter 4), and to develop and evaluate strategies to move the “regulated market” regime forward despite the ban on using animals in testing of psychoactive products (Chapter 9). During the process of analysis other relevant laws (i.e. Misuse of Drugs Act, Medicines Act, Dietary Supplement Regulations, and Food Act) and sources of law (i.e. judicial decisions), or their application (i.e. administrative decisions of the PSRA), were consulted.

Chapters 4 and 9 investigate legal terrain for a particular topic by applying legal reasoning to analyse statutes and other relevant sources of law. These chapters fall into the “mapping studies” category of Public Health Law Studies as outlined in Table 5 (page 35).

### **3.3.2 Interviews with key informants**

Individual interviews are a recognised data collection tool in applied policy research (Ritchie & Spencer, 2002). For this PhD, primary data were collected through face-to-face interviews with key stakeholders involved and/or affected by the implementation of the PSA and the establishment of the “interim” regulated market for psychoactive products. Key informants (KI) to be interviewed were identified through documentary analysis as outlined above. Individual interviews included:

1. Unstructured face-to-face interviews with six key policy actors to explore strategies to overcome the impasse created by the animal testing ban (Chapter 9).

It has been argued that the unstructured interview method can generate a breadth of data facilitating an in-depth understanding of interviewees’ perceptions about the complex social environment (Fontana & Frey, 2000). In this PhD study, unstructured interviews were used to explore policy stakeholders’ appreciation of the legal situation and how they saw their role in resolving the impasse following the imposition of the ban on animal testing in the process for approving products for a legal market. Data from interviews were triangulated with legal analysis (as explained above in section 3.2.1.3) and used to inform development of “scenarios” for the future of the PSA.

2. One-on-one semi-structured interviews with 30 key stakeholders about challenges experienced during the implementation of the interim regime.

The interviews aimed to explore issues experienced during the interim regime related to the regulation of products (Chapter 5), retail outlets (Chapter 6) and commercialisation of the market (Chapter 7). Interviews were conducted with politicians (4), civil servants (4), industry-related actors (5), health sector professionals (4), toxicologists (2), NGO and drug community services staff (5), local body representatives (2), health and drug policy academics (2), and law enforcement personnel (2).

The semi-structured interviews helped generate data of a codable nature, while also maintaining a conversational interview style. The interviews were recorded, transcribed and analysed thematically and the procedure for analysis is further explained in section 3.2.3. The interview guide, which was informed by the document analysis, is included in

Appendix C. Participant information sheet, consent form and the authority for the release of transcripts form are included in Appendices D, E and F respectively.

### **3.3.3 Thematic analysis of interview transcripts**

Thematic analysis is an analytical tool widely-used in social research, which aims to make sense of qualitative data (Braun & Clarke, 2006; Patton, 2015). It has been applied in many social science disciplines, including psychology, anthropology, and in more applied disciplines, including health, education and health policy evaluation (e.g. Huckel Schneider, Milat, & Moore, 2016). It is a flexible approach to data analysis which can be used across a range of epistemologies. In this PhD a highly pragmatic approach to thematic analysis was adopted, where the discourse and how views were presented was less important than the actual views and observations expressed by study participants. Consequently, analysis of interview transcripts is characterised by low-inference interpretation (Sandelowski, 2000).

The process for thematically analysing the transcripts of semi-structured interviews with key informants followed the 6-step approach proposed by Braun and Clarke (2006). This included: (1) familiarisation with the data (through transcribing recordings of interviews and re-reading the data); (2) coding the entire dataset by using specific well-defined labels (codes); (3) searching for broader themes by combining and refining the codes; (4) reviewing themes (i.e. checking themes against the dataset); (5) finalising themes (i.e. deciding the focus of each theme to determine the “story”); and (6) writing up (including contextualising the analysis within existing literature).

Coding and development of themes was approached deductively (with the interview guide as a coding framework) and inductively (coding directed by data content) (Patton, 2015). NVivo 10 qualitative data management software was used to assist the process of thematic analysis.

### **3.3.4 Statistical analysis of data from NZ-ADUM**

Chapter 8 uses data from a survey of police arrestees interviewed as part of the New Zealand Arrestee Drug Use Monitoring study (NZ-ADUM) conducted at the SHORE & Whāriki Research Centre. Each year, the NZ-ADUM study surveys approximately 800 police arrestees about their drug use at four central city police stations in New Zealand (i.e. Whangarei, Auckland Central, Wellington Central and Christchurch Central). Potential participants include arrestees who have been detained at a police station for less than 48 hours. Interviewing is conducted by civilian

researchers in a private room and confidentiality is ensured. The author of this PhD was involved in the project management of the study over the time of data collection.

Since 2014, NZ-ADUM study participants have been asked to rate perceived health risks and social acceptability of a number of legal and illegal drugs, including approved and unapproved legal high products. Statistical analysis of these data was undertaken to explore whether government approval of psychoactive products resulted in reduced risk perceptions and increased social acceptability of “legal highs”, and whether personal characteristics (current drug use and sociodemographic characteristics) impacted these appreciations. The statistical analysis required to answer these questions was planned by the PhD candidate and undertaken by a statistician employed at the SHORE & Whāriki Research Centre.

This analysis explored the effect of law on environment (in this context the term “environment” is used in a broad sense and refers to social environment), and is represented along Path C in Figure 6 (page 32). This “natural experiment” (Burriss et al. (2010) use the term “intervention study”, see Table 5, page 35) was undertaken to further explore to what extent establishment of a “regulated market” for NPS influenced social perceptions about risks and acceptability of interim approved products.

### **3.3.5 Review of academic literature**

The international drug policy literature, in particular the literature on NPS laws and policies and the developments with new legal regimes for recreational cannabis in a number of US states, Uruguay and Canada, has been monitored continuously through the course of this PhD study. Reviews of academic literature have been used to inform the discussions in the published papers as well as in the introductory and concluding chapters of this PhD dissertation.

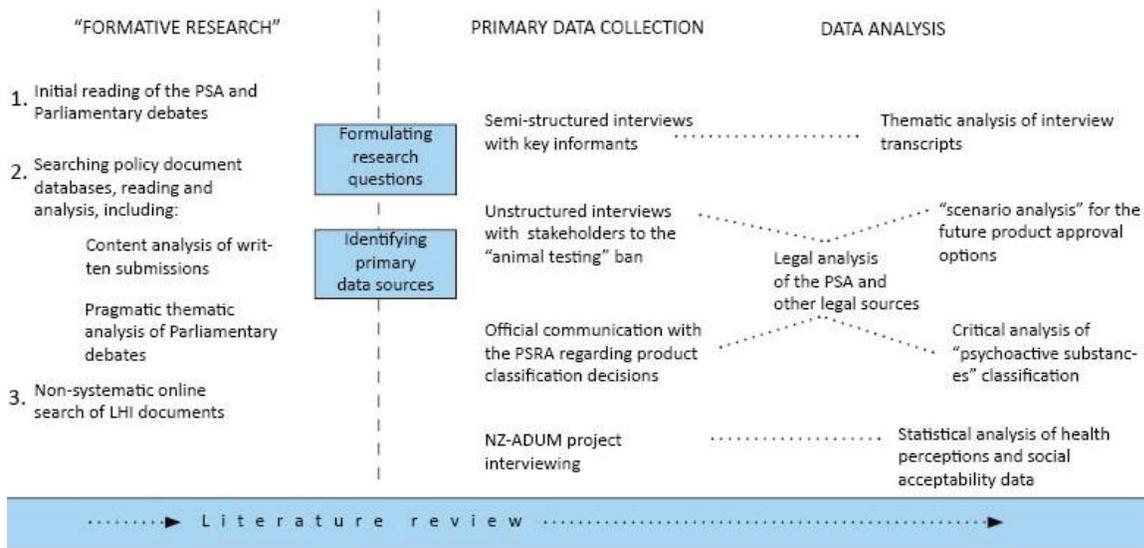


Figure 7: Research process flowchart

## **Chapter 4: What products are considered psychoactive under New Zealand’s regulated legal market for new psychoactive substances (NPS, ‘legal highs’)? Implications for law enforcement and penalties**

This chapter investigates how the definition of “psychoactive substance” is operationalised in the New Zealand legal context and thus provides overall background to the legislative environment in which the PSA operates. The paper comprising this chapter examines how products with psychoactive properties are categorised under different pieces of legislation (e.g. PSA, Misuse of Drugs Act, Medicines Act, Dietary Supplement Regulations, Food Act) and discusses the implications of these different legal classifications for law enforcement. It concludes with a number of practical recommendations on how to more clearly categorise products with psychoactive properties under the current system. The early-view version of this paper was published online in February 2016 in *Drug Testing and Analysis*. Findings were also presented at the sixth annual *National Addiction Research Symposium*, Auckland, New Zealand (22 April 2015).

The issue of categorising products with broadly the same ingredients under multiple different regulatory regimes extends beyond the PSA legislation. In a letter published in the *New Zealand Medical Journal* I discuss how this applies to *cannabis sativa* (Appendix G). In this letter I argue that certain non-psychoactive cannabis-derived products which may have potential health benefits (e.g. Elixinol™, which is an 18% CBD oil extracted from industrial hemp) could be regulated under the framework for dietary supplements in New Zealand, thus eliminating the need to provide extensive evidence for approval as a pharmaceutical product.

Since publication of the *Drug Testing and Analysis* paper and *New Zealand Medical Journal* letter, steps have been taken to clarify the legal status of some plants with psychoactive properties. In April 2016, the PSRA published a list of 31 plant species which they consider are not covered under the PSA (PSRA, 2016). The list was compiled based on the PSRA's understanding that it is not the intention of the PSA to cover these plants and some plants are included in the draft list of ingredients permitted to be marketed under a new regime for regulation of dietary supplements (second reading in New Zealand Parliament). I provided further critique of this approach in a letter to the Editor published in *Addiction* journal (see Appendix H).

Rychert, M., & Wilkins, C. (2016). What products are considered psychoactive under New Zealand's legal market for new psychoactive substances (NPS, 'legal highs')? Implications for law enforcement and penalties. *Drug Testing and Analysis*, 8(8), 768-778. Doi:

10.1002/dta.1943

## Abstract

The problem of defining what 'psychoactive' products and substances should be covered by legislation aimed at controlling new psychoactive substances (NPS; legal highs) is central to the current debate on designing new legislative responses to NPS. In New Zealand, implementation of the Psychoactive Substances Act 2013 (PSA) revealed uncertainties about what psychoactive products are covered by the new regime, with important implications for legal penalties. We reviewed five pieces of legislation which can cover substances with psychoactive properties: PSA, Misuse of Drugs Act (MODA), Food Act, Dietary Supplements and Medicines Act. Our analysis revealed a number of psychoactive substances which are not MODA-scheduled may potentially fall under more than one regulatory regime, including kava, *Salvia divinorum*, nitrous oxide, 25I-NBOMe and 1,3-dimethylbutylamine (DMBA). For example, kava may be classified as a food, dietary supplement, herbal remedy or a psychoactive substance, depending on how it is presented (including advertising and labelling). There are considerable differences in penalties and regulatory requirements between the different legislative regimes, and these may result in unnecessary prosecutions or 'gaming' of the system. We discuss a number of ways to more clearly categorise products, including a public schedule of psychoactive substances and products, demarcation criteria based on the quantity of active ingredient and demarcation based on 'discernible intoxication'. Routine use of forensic testing is essential to ensure appropriate prosecutions and penalties. Robust safety standards are also required in legislative regimes exempted from psychoactive substances regime to prevent "creative compliance".

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## Introduction

Over the last decade there has been a steady rise in the number of new psychoactive substances (NPS) identified in Europe and around the world (Brandt et al., 2014; EMCDDA, 2015a; UNODC, 2015), with many sold as so called ‘legal highs’(UNODC, 2013a). These products have posed a considerable challenge to traditional drug control systems as the number of NPS compounds overwhelms any attempt at risk assessment on a substance-by-substance basis, and there is typically little human pharmacological and toxicological data available on their risks to justify their scheduling in domestic drug laws (EMCDDA, 2015c; L. A. King, 2014; UNODC, 2013a).

In an attempt to end the ongoing cat-and-mouse game, a number of countries have imposed ‘blanket bans’ on the supply of all substances with psychoactive properties. Legal definitions used in these innovative laws typically fall into one of the two broad categories: purpose-based definitions, when substances are controlled if they may be used instead of, or for the same purpose as controlled drugs (e.g. Poland (Hughes & Malczewski, 2011; Kapka-Skrzypczak et al., 2011) Romania (Hughes & Griffiths, 2014)); or effects-based definitions, which refer to the capability of a substance to influence the user’s mind, mood, brain or behaviour (e.g. Ireland (Kavanagh & Power, 2014) Australia (*Crimes Legislation Amendment (Psychoactive Substances and Other Measures) Act 2015*; Intergovernmental Committee on Drugs, 2014)). These so-called ‘catch all’ responses have raised issues about the breadth of definitions used in the law and the scope of products potentially subject to new legislation (Nutt et al., 2015; Stevens et al., 2015). Most recently in the United Kingdom, there has been concern that a proposed blanket ban on products that induce psychoactive effects (House of Lords, 2015) could also cover a range of common products such as perfumes, flowers and petrol fumes (Advisory Council on the Misuse of Drugs, 2015; Home Affairs Committee (House of Commons), 2015; Nutt et al., 2015; Scott, 2015; Stevens et al., 2015). The UK NPS Expert Panel stressed the need to ensure that “(i) definitions used in such legislation are robust; (ii) required exemptions are addressed; (...) and (iv) potential unintended consequences are explored more fully” (UK NPS Review Expert Panel, 2014).

New Zealand’s Psychoactive Substances Act (PSA) 2013 is the world’s first law designed to control NPS by means of a regulated market for approved psychoactive products (New Zealand Parliament, 2013a; Wilkins, 2014a). Under this regime, sponsors can gain approval to legally manufacture and sell psychoactive products if they prove through toxicology and clinical trials that the proposed products are “low risk” (PSRA, 2014a). The ongoing implementation of the PSA and the operation of the interim legal market for NPS between July 2013 and May 2014

(Bell, 2015; Wilkins, 2014b; Wodak, 2014) raised questions about which substances and products are covered by the PSA, and which products, despite inducing psychoactive effects, are covered by other legal regimes (such as the Misuse of Drugs Act, Medicines Act, or Dietary Supplements Regulations). The PSA contains an effects-based definition, which covers any substance, mixture, preparation, article, device or thing capable of having an effect (by any means) on the mind of an individual who is using the substance (s. 8, 9(1) PSA), irrespective of its harm. A range of substances and products are excluded from this definition: (i) controlled drugs and drug precursors specified or described in schedules of the Misuse of Drugs Act, (ii) medicines, (iii) herbal remedies, (iv) dietary supplements, (v) food, (vi) alcohol (unless the alcohol contains a psychoactive substance that is not alcohol), and (vii) tobacco products (unless the tobacco product contains a psychoactive substance [other than nicotine]) (s. 9(3) PSA). Exemptions have allowed the continued trade of certain psychoactive products, such as energy drinks, coffee, camomile tea, tobacco and alcohol beverages (MOH, 2012; New Zealand Health Committee, 2013). However, uncertainties have also resulted about the legal status of some products, which fall at the borders of legislative regimes. While the legislative frameworks are mutually exclusive, some products may fall under the definitions of the PSA and other pieces of legislation as well; for example, when a product is psychoactive and represented as a dietary supplement, or as having therapeutic properties.

This paper investigates how substances and products with potential psychoactive effects are classified under the PSA and various other pieces of legislation in New Zealand, and what impact this classification has on law enforcement and penalties. We performed content analysis of five pieces of legislation (Burris et al., 2010; Tremper et al., 2010) which can potentially cover products with psychoactive effects in New Zealand: PSA, Misuse of Drugs Act (MODA), Food Act (FA), Dietary Supplements Regulations (DSR) and Medicines Act (MA). Borderline products were discussed with the Medicines and Medical Devices Safety Authority (MedSafe) and the Psychoactive Substances Regulatory Authority (PSRA), the health agency established to manage the PSA regime. Enforcement procedures, recent case law, and penalties for offending under respective laws were then examined in order to evaluate the practical implications of different legal classifications. The issue of demarcation between the regime for control of NPS and other laws will be of interest to countries which may be contemplating new pro-active legislative approaches to legal highs.

## Ambiguities in legal classifications of products with psychoactive properties

An initial reading of legislation suggests that substances with psychoactive properties may fall under a number of broad definitions included in different pieces of legislation (Figure 8, Table 6). We identified five specific substances with psychoactive properties which are not MODA-scheduled and may potentially fall under more than one regulatory regime, including the PSA: (i) kava (*Piper methysticum*), (ii) *Salvia divinorum*, (iii) nitrous oxide, (iv) 25I-NBOMe and (v) 1,3-dimethylbutylamine (DMBA). These were used as examples to explore how legislative overlaps are being resolved in practice. Table 7 contains a summary of their official classification as of late-2015.

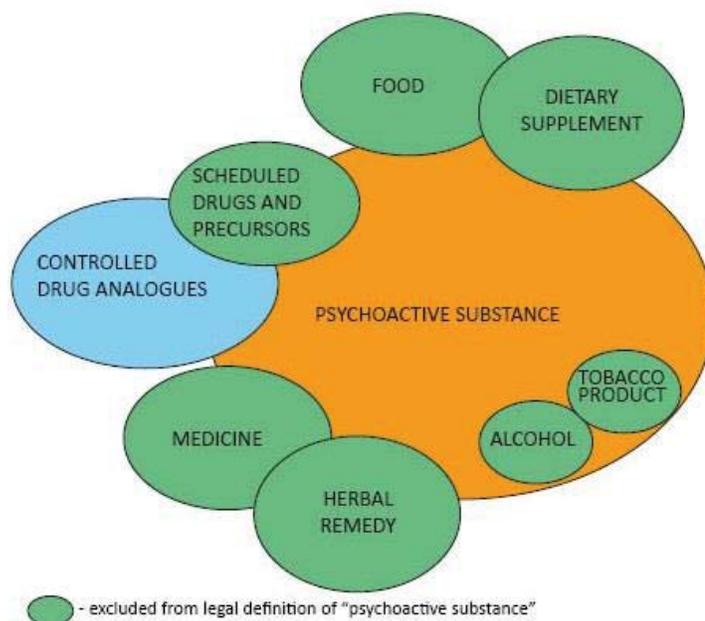


Figure 8: Schematic representation of relationships between definitions of psychoactive substance and other products with potential psychoactive properties

### Kava (*Piper methysticum*)

Kava is a psychoactive plant traditionally used in Pacific cultures (Cawte, 1985; Showman et al., 2015). Due to its sedative properties (Sarris, LaPorte, & Schweitzer, 2011) kava has been also widely used in the treatment of anxiety (Pittler & Ernst, 2003; Sarris et al., 2013) but reports of hepatotoxicity (Fu, Xia, Guo, Yu, & Chan, 2008; Teschke, Schwarzenboeck, & Akinci, 2008) led to restrictions in many countries (Clouatre, 2004). Contemporary use has extended beyond traditional and medicinal settings (McDonald & Jowitt, 2000) to recreational use (Baker, 2012;

Showman et al., 2015) with 6.3% of New Zealanders (aged 16-64 years) reporting ever using kava recreationally (MOH, 2010).

In response to growing concerns about the influence of the PSA on ceremonial practices of Pacific communities in New Zealand (New Zealand Parliament, 2013b) the Government clarified that kava products would remain widely available on the legal market. They explained that kava is regulated as food (when represented as a drink), a dietary supplement (when capsules are marketed for their nutritional value) and as a herbal remedy (if linked to therapeutic use) (New Zealand Government, 2013a). However, when linked to recreational use, kava products are covered by the PSA (PSRA, personal communication, 24 April 2015). Indeed, a recreational product containing kava received a temporary license during the interim PSA regulatory regime (Table 7) (PSRA, no date; Wilkins, 2014b). This legal classification remains valid, while the actual legality of supply and possession depends on a regulatory approval for the product, or lack of thereof.

**Table 6: Categories of products or substances exempted from the PSA regime**

Product/substance	Legal definition	Legal Act (and abbreviation)	
DIETARY SUPPLEMENT	- something to which the following clauses apply: (1) It is an amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin; (2) It is sold by itself or in a mixture; (3) It is sold in a controlled dosage form as a liquid, powder, or tablet (...); (4) It is intended to be ingested orally; (5) It is intended to supplement the amount of the amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin normally derived from food.	Dietary Supplements Regulations 1985, s.2A	(DSR)
FOOD	- anything that is used or represented for use as food or drink (...)	Food Act, 1981, s.2	(FA)
MEDICINE	- any substance or article that is sold (...) for administering to human beings for a therapeutic purpose; and achieves its principal intended action by pharmacological, immunological, or metabolic means	Medicines Act 1981, s.3(1)	(MA)
HERBAL REMEDY	- a medicine (...) consisting of— (a) any substance produced by subjecting a plant to drying, crushing, or any other similar process; or (b) a mixture comprising 2 or more such substances only; or (c) a mixture comprising 1 or more such substances with water or ethyl alcohol or any inert substance	Medicines Act 1981, s.2(1)	(MA)
TOBACCO PRODUCT	- any product manufactured from tobacco and intended for use by smoking, inhalation, or mastication; and includes nasal and oral snuff (...)	Smoke-free Environments Act 1990, s. 2(1)	-

ALCOHOL	alcohol means a substance— (a) that— (i) is or contains a fermented, distilled, or spirituous liquor; and (ii) at 20°C is found on analysis to contain 1.15% or more ethanol by volume; or (b) that— (i) is a frozen liquid, or a mixture of a frozen liquid and another substance or substances; and (ii) is alcohol (within the meaning of paragraph (a)) when completely thawed to 20°C; or (c) that, whatever its form, is found on analysis to contain 1.15% or more ethanol by weight in a form that can be assimilated by people	Sale and Supply of Alcohol Act 2012, s.5(1)	-
SCHEDULED DRUGS AND DRUG PRECURSORS	- drugs specified or described in Schedule 1, 2, or 3 of the MODA and precursor substances specified or described in Schedule 4 of the MODA	Misuse of Drugs Act 1975, schedules	(MODA)

### Salvia divinorum

Salvia divinorum is a hallucinogenic plant indigenous to southern Mexico (Casselmann, Nock, Wohlmuth, Weatherby, & Heinrich, 2014) where traditional therapeutic usage (Prisinzano, 2005; Vortherms & Roth, 2006) involves chewing fresh leaves and drinking salvia tea (González, Riba, Bouso, Gómez-Jarabo, & Barbanoj, 2006; Griffin, 2014). It emerged as a recreational drug in the 1990s (Casselmann et al., 2014). In this context salvia is smoked producing a strong hallucinogenic effect with immediate onset and short duration (González et al., 2006; Lange, Daniel, Homer, Reed, & Clapp, 2010). Reported adverse effects include anxiety and psychological distress (Rosenbaum et al., 2012). In New Zealand, salvia preparations were recommended for scheduling under the MODA “restricted substances” regime in 2008 (Expert Advisory Committee on Drugs, 2007; Wilkins, 2011), but the proposal never progressed leaving them widely available on the pre-PSA unregulated legal high market. In 2012, 56% of frequent ecstasy users reported they had used salvia divinorum at some point in their lives (Wilkins et al., 2015).

Following the passage of the PSA, most retailers appeared to have voluntarily withdrawn salvia smoking products under the understanding that it is an unapproved psychoactive substance. The PSRA confirmed this interpretation (personal communication, 4 November 2014). However, salvia remains available for sale as a live plant. The PSRA confirmed that psychoactive plants in live form are not covered by the PSA (personal communication, 14 April 2015). This comes from the application of the MODA, where live plants containing controlled substances are generally not prohibited (with the exceptions of cannabis, opium poppies, coca trees, and peyote cactus (MODA, s. 2). The PSRA also confirmed that salvia products would be excluded from the PSA regime if they are represented as herbal remedies and comply with relevant provisions of the MA (see conditions for sale in Table 7) (personal communication, 4 November 2014).

**Table 7: Psychoactive substances which can potentially sit in multiple regulatory regimes**

substance	Product marketing	Official legal classification	Conditions for sale
Kava ( <i>Piper methysticum</i> )	Kava beverage	food	<ul style="list-style-type: none"> <li>- No pre-approval</li> <li>- Beverage obtained by suspension of kava using cold water only (no organic solvent allowed) (Food Standards Code, standard 2.6.3)</li> </ul>
	Capsules containing kava powder	dietary supplement	<ul style="list-style-type: none"> <li>- No pre-approval</li> <li>- Needs to comply with the definition:                             <ul style="list-style-type: none"> <li>(a) it is amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin AND</li> <li>(b) sold in a controlled dosage form as a liquid, powder or tablet AND</li> <li>(c) intended to be ingested orally AND</li> <li>(d) intended to supplement amount of the amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin normally derived from food</li> </ul> </li> </ul>
	Dried kava root sold for therapeutic purpose	herbal remedy	<ul style="list-style-type: none"> <li>- No pre-approval</li> <li>- Must be offered for therapeutic purpose</li> <li>- Labelling limited to designation of plant and process to which it was subjected, no written recommendation as to the use</li> <li>- Must be offered by healthcare professional, natural therapist or equivalent after request of an individual</li> </ul>
	<i>Dr Feelgood</i> : Mix of amino acids, kava, caffeine and citrus aurantium extract	psychoactive substance	<ul style="list-style-type: none"> <li>- Needs to be approved by the PSRA (license revoked by the Psychoactive Substances Amendment Act)</li> <li>- R18* purchase</li> <li>- Sell only in licensed retail outlets</li> <li>- Labelling restrictions</li> <li>- Advertising restrictions</li> </ul>
<i>Salvia divinorum</i>	Dried salvia divinorum leaves, therapeutic purpose	herbal remedy	<ul style="list-style-type: none"> <li>- No pre-approval</li> <li>- Must be offered for therapeutic purpose</li> <li>- Labelling limited to designation of plant and process to which it was subjected, no written recommendation as to the use</li> <li>- Must be offered by healthcare professional, natural therapist or equivalent after request of an individual</li> </ul>
	Live salvia plant	horticultural product	<ul style="list-style-type: none"> <li>- No specifications</li> </ul>
	<i>Mexican Trippin Weed</i> : dried salvia leaves extract x7	psychoactive substance	<ul style="list-style-type: none"> <li>- Needs to be approved by the PSRA</li> <li>- R18* purchase</li> <li>- Sell only in licensed retail outlets</li> <li>- Labelling restrictions</li> <li>- Advertising restrictions</li> </ul>
Nitrous oxide	Medical inhalant	prescription medicine	<ul style="list-style-type: none"> <li>- medical purpose; consent of the Minister of Health required prior to marketing; product evaluated by MedSafe and registered</li> </ul>
	Inhalant for recreational use	Non-compliant prescription medicine	<ul style="list-style-type: none"> <li>- N/A (always prohibited)</li> </ul>
25I-NBOMe	Marketed as LSD	class A drug	<ul style="list-style-type: none"> <li>- N/A (always prohibited)</li> </ul>
	Recreational NBOMe tabs	psychoactive substance	<ul style="list-style-type: none"> <li>- Needs to be approved by the PSRA</li> <li>- R18* purchase</li> <li>- Sell only in licensed retail outlets</li> <li>- Labelling restrictions</li> <li>- Advertising restrictions</li> </ul>
DMBA (1, 3-dimethylbutylamine)	Pre-workout gym supplement <i>Frenzy</i> containing DMBA	psychoactive substance	<ul style="list-style-type: none"> <li>- Needs to be approved by the PSRA</li> <li>- R18* purchase</li> <li>- Sell only in licensed retail outlets</li> <li>- Labelling restrictions</li> <li>- Advertising restrictions</li> </ul>

\* R18 – restricted to customers 18 years old and over

## **Nitrous oxide (N<sub>2</sub>O)**

Nitrous oxide, commonly known as 'laughing gas', is used in medicine (volatile anaesthetic), by the food (whipped cream dispensers), and automotive industries (engine accelerant) (O'Sullivan & Benger, 2003; Tarver, 2010). Inhaling the gas for its euphoric effects, first reported among medical professionals in the 19th century (A. G. Thompson, Leite, Lunn, & Bennett, 2015), gained popularity among contemporary "legal high" users (Cousaert, Heylens, & Audenaert, 2013) largely due to the wide availability of N<sub>2</sub>O canisters used in cream dispensers and home soft drink machines. Prolonged use has been linked to neurological complications (Alt, Morrissey, Gang, Hoffman, & Schaumburg, 2011; Cousaert et al., 2013; A. G. Thompson et al., 2015). In New Zealand, 12% of first-year university students reported recreational use of nitrous oxide in 2003 (Ng, O'Grady, Pettit, & Frith, 2003). In 2006, 47% of frequent ecstasy users reported using nitrous oxide in the previous six months (Wilkins et al., 2015). In the mid-2000s, the gas was increasingly sold as a 'legal high' from 'NOS bars' and convenience stores. This led the Ministry of Health to write to retailers explaining nitrous oxide was a medicine and hence illegal to sell for recreational use, and this curtailed its sale from convenience stores (New Zealand Government, 2005a, 2005b; Wilkins & Sweetsur, 2009, 2013). While this seemingly prohibited sale of all non-medicinal N<sub>2</sub>O products, the Ministry of Health clarified that only the sale of inhalants for recreational use would be targeted, allowing the sale of food-grade nitrous oxide chargers to continue (MOH, 2005).

Passage of the PSA has not affected the legal status of nitrous oxide inhalants. Even when supplied for recreational use, nitrous oxide inhalants remain classified as "prescription medicines" and fall under the MA (PSRA personal communication, 13 April and 24 April 2015). Consequently, the substance cannot be regulated under the PSA regime. Selling, using and possessing nitrous oxide inhalant for recreational purpose are offences under the MA (Table 7) and corresponding penalties apply (Table 8). This shows that psychoactive substances classed as prescription medicines are exempt from application of the PSA, even when they are purchased and sold for their psychoactive effects. The classification under MA stands even when consent for distribution of a specific medicine has been revoked. For example, sibutramine, a weight-loss drug which appears to exert its action by mechanisms similar to classic anti-depressants (Arfken, Schuster, & Johanson, 2003), continues to be classified under the MA (PSRA, personal communication, 20 October 2015), despite reports of side effects leading to its withdrawal as a licensed prescription medicine in 2010 (MedSafe, 2010).

## **DMBA (“Frenzy”)**

1,3-dimethylbutylamine (DMBA) is a synthetic stimulant, analogue of 1,3-dimethylamylamine (DMAA), which has emerged as an ingredient in dietary supplements. The products are marketed as improving athletic performance and weight loss (Cohen, Travis, & Venhuis, 2015a, 2015b). In late 2014 at least three such products, positioned as pre-workout supplements (Frenzy, Unstoppable, Pre War), were identified in New Zealand.

The way these products were presented suggested that they fell under the DSR regime and its penalties. However, the products were voluntarily recalled after the PSRA contacted retailers informing them that the supplements were considered to be unapproved psychoactive products (PSRA, 2015a). Psychoactivity of DMBA was established by the PSRA on the grounds of structural and functional similarity to DMAA, which is itself considered to be a psychoactive substance (PSRA, 2015a). The PSRA concluded that the products are not covered by the dietary supplement exception because they “contained a substance which is not part of a normal diet” (personal communication, 13 April 2015).

The concept of dietary properties is a broad one, with caffeine tablets, St John’s Wort pills and kava capsules some of the products with psychoactive properties currently covered by the DSR. In the past, a dietary supplement and ‘herbal’ energy drink containing BZP (then unscheduled) (Bassindale, 2011) were also considered to fall under the DSR and FA provisions (NZLC, 2010). The blurry line between definition of psychoactive substance and dietary supplements hinders attempts to control potential psychoactive products before they enter the market, something which the PSA is intended to achieve.

## **25I-NBOMe**

25I-NBOMe is the most commonly reported drug of the NBOMe series (UNODC EWA, 2014), a group of hallucinogenic derivatives of the 2C class of phenethylamines first synthesised in the 2000s (Heim, 2003; Heim & Elz, 2000; Lawn, Barratt, Williams, Horne, & Winstock, 2014; Wood, Sedefov, Cunningham, & Dargan, 2015). 25I-NBOMe has reportedly been sold as lysergic acid diethylamide (LSD) or as a ‘legal’ alternative to LSD (Caldicott, Bright, & Barratt, 2013; EMCDDA, 2014; Lawn et al., 2014; Wood et al., 2015). Its use has been associated with severe adverse effects including agitation, tachycardia and hypertension, and three deaths associated with its use were reported in the EU in 2013 (EMCDDA, 2014; Suzuki et al., 2015; Wood et al., 2015).

Since their appearance on the New Zealand market in early 2012, the legal status of NBOMe compounds has been subject to a number of reviews. Initially, the Institute of Environmental Science and Research (ESR) concluded they fell under the “controlled drug analogue” definition included in MODA as their structure was considered to be “substantially similar” to a class A scheduled drug, DOB (2,5-dimethoxy-4-bromoamphetamine) (Institute of Environmental Science and Research, 2013). The ESR reversed their opinion following receipt of new evidence from a reference standard. As a result, since mid-2013 NBOMe compounds have no longer been considered controlled drug analogues (Institute of Environmental Science and Research, 2013) but “psychoactive substances” under the PSA. In March 2015, the Commission on Narcotic Drugs placed 25I-NBOMe, 25B-NBOMe and 25C-NBOMe under international control (UNODC EWA, 2015) and consequently these substances are expected to be scheduled under MODA in New Zealand in the near future.

## **The role of marketing and labelling in the classification of psychoactive products**

The legal classification of a product determines the conditions of its sale and use (if any) and what sanctions apply if regulatory provisions are breached. Given disparities in requirements for legal sale and sanctions for non-compliance under the PSA and some of the exempted regimes (Table 8), manufacturers and retailers may continue to use these laws as a way to “workaround” the new regime, and thereby avoid the product testing and registration requirements under the PSA, as well as a way of avoiding higher penalties under the PSA.

Such “creative compliance” depends on how products and substances are classified by the authorities. The existing official guidelines on classification of consumer and medicinal products refer to broad legal definitions (MedSafe, no date). Further discussion with the PSRA about the cases outlined in this paper indicated that the regulatory regime applied “depends on how the product is presented (product formulation, labelling, instructions for use, dose form, advertising, and so on) and whether it meets the requirements of that regime” (personal communication, 4 November 2014). This raises the question whether place of sale (i.e. sale from legal high stores, health food shops, sports shops or gyms) is considered to be part of “product presentation” criterion. A lawyer representing the legal high industry suggested this could result in any product sold from a legal high store potentially being covered by the PSA (personal communication, 10 October 2014).

The draft Psychoactive Substances Product Approval Guidelines specify that “any product sold or promoted as being able to produce psychoactive effect (whether psychoactive effect is direct or implied, e.g. by use of word “high”) meets the definition of a psychoactive substance, irrespective of the ingredients it contains, and must have the Authority’s consent before it can be sold” (PSRA, 2014a). This suggests that products can be legally considered psychoactive based solely by virtue of their presentation. However, the case of “Tai High”, a smokeable product containing the incense Damiana and sold in bright packaging, does not support this interpretation. “Tai High” remains legally available as the PSRA concluded it does not induce a psychoactive effect, and hence doesn’t meet the definition of “psychoactive substance” in the PSA (Christian, 2014). Products with only an implied psychoactive claim may be subject to other regulations, such as the Fair Trading Act 1986 (PSRA, 2014a).

**Table 8: Maximum penalties for offences under DSR, FA, MA, PSA and MODA**

	Dietary Supplements Regulations	Food Act	Medicines Act	PSA	MODA			
Example of prohibited or non-compliant product:	Mislabeled dietary supplement	Food injurious to health or harmful	Prescription medicine sold without authorisation or possessed/used without "reasonable excuse"	Unapproved psychoactive substance (unknown risk)	Controlled drug analogue, i.e. any drug with structure substantially similar to a scheduled drug (unknown risk)	Class C drug ("moderate risk")	Class B drug ("high risk")	Class A drug ("very high risk")
Supply/dealing	Fine not exceeding NZD 500 (+ \$50 for every day onwards) (DSR, s.21)	Fine NZD 5,000 (FA, s. 9) 1 year if "knowing that will create risk to human health" (FA, s. 11AA)	Fine up to NZD 40,000 or up to 6 months (MA, s. 18(1) and (5))	2 years	8 years	8 years	14 years	lifetime
Possession	-	-	3 months or fine up to 500 NZD (MA, s. 43(1), s. 78)	300 NZD on-the-spot civil fine or 500 fine by court ("infringement offence")	3 months and/or 500 NZD	3 months and/or 500 NZD	3 months and/or 500 NZD	6 months and/or 1,000 NZD
Use*	-	-	3 months or fine up to 500 NZD (MA, s. 43(1), s. 78)	-	3 months and/or 500 NZD (with presumption against imprisonment)	3 months and/or 500 NZD (with presumption against imprisonment)	3 months and/or 500 NZD	6 months and/or 1,000 NZD
	← Decreasing sanctions			PSA	Increasing sanctions →			
	REGULATORY APPROACHES				PROHIBITORY APPROACHES			

\*Despite the UN drug conventions do not distinguish between the use and possession of drugs, many countries specify the use of drugs as a punishable offence separate from possession, including about half the countries in Europe (EMCDDA, 2015d). The practical implication is that, when use is punished, the mere fact of being under the influence of a substance may provide new powers to the police (when the actual substance or product is not available), such as the ability to take biological samples (EMCDDA, No date).

## Implications for policing and prosecuting in criminal cases

The classification of a substance under the PSA or MODA will determine what type of legal response offences receive. For supply offences, the legal regime determines the severity of criminal punishment; for personal possession offences, it determines type of legal responsibility (criminal vs. administrative); and for use offences, it determines whether the behaviour is prohibited at all (Table 8).

In 2014, the number of recorded offences for the supply of a 'non-approved psychoactive product' under the PSA (i.e. possession for sale, offering to sell, sale) was considerably lower (n=140) than the number of corresponding offences for most scheduled drugs, including cannabis (n=1,603), methamphetamine and amphetamine (n=1,200) or ecstasy (n=243). Similarly, the number of personal possession offences recorded under the PSA (n=90) was much lower than the number of offences recorded for personal possession and use of some scheduled drugs, such as cannabis (n=5,231), methamphetamine and amphetamine (n=892), but exceeded figures for other drugs such as ecstasy (n=50) or LSD (n=63) (Statistics New Zealand, no date).

Given that users may be unaware of the chemical composition of the recreational drugs they purchase, consume and handle, they may inadvertently admit to committing a more serious offence. For example, an offender who believed they had purchased MDMA may choose to plead guilty to possession of this scheduled drug, while in reality they may have merely possessed an unapproved psychoactive substance. Given financial and time constraints, law enforcement are unlikely to conduct forensic testing in one-off personal possession cases and would most likely accept an offender's testimony (National Drug Intelligence Bureau, personal correspondence, 25 September 2014). As a result, NPS users may plead guilty to more serious criminal drug charges if they are unaware of the actual substances they possess. It also creates the possibility that people possessing scheduled drugs will try to "game the system" by claiming to have acted under the PSA regime, in other words possessed an unapproved NPS.

The problem extends to supply cases. A recent prosecution 'Operation Model' showed that in specific circumstances MODA charges may apply to PSA offenders. In this case a group of offenders selling NBOMe compounds as LSD (a Class A drug) was prosecuted for 'offering to supply a Class A drug'. Charges in this case were consistent with previous case law in illegal drug cases, which had established that offering to supply non-controlled substances (such as herbal mixes, legal party pills, "pale yellow crystals") as scheduled drugs will be prosecuted as drug supply offences (cases R v Brown, R v Paul, R v Wilson, R v Thompson, R v Johnson) . The reasoning is in line with the purpose of MODA which is to suppress the demand for scheduled drugs which offering for sale can stimulate. However, because the offenders in 'Operation Model' were referring to the tabs in slang terms rather than as LSD specifically (National Drug Intelligence Bureau, personal correspondence, 3 October 2014), it is debatable whether the prosecution under MODA would have been successful without the offenders' guilty plea.

Alternatively, suppliers may try to avoid MODA charges by insisting they thought that they were dealing in "psychoactive substances" rather than drugs controlled under MODA. Such a defence

was employed by a group of offenders following the 2011 police investigation 'Operation Ark'. Defendants claimed that they believed that the substance they imported and dealt with was not controlled under MODA and to this end a reference to the PSA was made. The substance in this case (4-methylethcathinone, i.e. 4-MEC) was judged to fall under the MODA "controlled drug analogue" definition, which covers substances with a chemical structure "substantially similar" to scheduled drugs. The defendants' mistake as to whether 4-MEC was "substantially similar" to class B drug methcathinone was considered an error of law, and therefore did not provide a successful defence (case *R v Chase*). The case highlights the potential for overlap between definitions of "controlled drug analogue" and "psychoactive substance", and the challenges in applying these definitions in judicial practice, as both of them rely on expert opinion on the structural similarity or psychoactivity of a compound.

A more recent example of case law deals with determination of psychoactivity in court and showcases how exemptions from the PSA may be used by defence lawyers. In a recent appeals case, offenders convicted of 'possessing a non-approved psychoactive substance for supply' challenged the judgement on the grounds that: (1) the substances in question (i.e. JWH-018 and JWH-200) were wrongly determined as psychoactive, and (2) even if they were found to be psychoactive, they were actually 'herbal remedies' and hence exempt from the PSA. The appeals judge was satisfied that descriptions of mood change (i.e. "elevated mood" and "a feeling of well-being") as well as the general similarity of synthetic cannabinoids to natural cannabis, as provided in the expert statement, were sufficient to meet the legal definition of psychoactivity. The expert statement referred to chemical and pharmacological effects of the compounds and relied on available scientific literature on JWH-018 and JWH-200. The second ground for appeal, i.e. the exclusion under herbal remedy exception, was rejected as "a strained interpretation" (case *Mihinui & Anor v New Zealand Police*). The case raises an important question of how psychoactivity will be proved by the prosecution in the case of an entirely new substance with no scientific literature at all, or natural analogy with existing drug types. The Institute of Environmental Science and Research (ESR) does not have the ability to test whether a substance is psychoactive, and any advice on psychoactive effects is based on chemistry and/or similarity to other substances (Institute of Environmental Science and Research, 2013).

## **Psychoactive substances vs controlled drug analogues**

The definition of controlled drug analogue under MODA has been applied to a range of NPS in New Zealand, notably in the case of mephedrone (4-methylmethcathinone, i.e. 4-MMC) and more recently alpha-PVP, methoxetamine, MDPV, and 4-MEC. Analogue provisions take

precedence over the PSA, i.e. unauthorised use, possession and supply of a substance structurally analogous to a scheduled drug are controlled under MODA, as class C drug offences.

From a regulatory perspective, however, the use of a controlled drug analogue in a psychoactive product for regulatory approval is allowed (PSRA, personal communication, 6 November 2014). This is because passage of the PSA came with an amendment to MODA, under which “approved psychoactive products” are excluded from the definition of a “controlled drug analogue”. This legislative design aimed to give legal certainty to the industry in case a new drug gets scheduled and subsequently the substance used in a previously approved product becomes a “controlled drug analogue”. In practice, it means that substances falling under the “controlled drug analogue” definition and not specified in MODA schedules now have a chance to be re-evaluated and regulated under the PSA (provided the substance is not analogous to a Class A drug).

## **Conclusions and discussion**

Our analysis suggests that the legal status of some products with psychoactive effects may be uncertain and current rules for classification are open to interpretation. The role of product presentation and the legal requirements under different regulatory regimes create difficulties in determining which legislative regime covers a given psychoactive product, and what sanctions (if any) apply in the case of non-compliance. This undermines the principle of legal certainty which allows consumers and entrepreneurs to shape their behaviours according to clear legal rules. A public registry of products with psychoactive effects considered to be covered and excluded from the PSA would be a useful first step toward improving certainty. The Psychoactive Substances Expert Advisory Committee (PSEAC), an expert body established to advise the PSRA on products approval decisions, could provide advice on “borderline products”. The PSEAC could also develop a list of substances which are deemed to be psychoactive, and which could not be used as ingredients in products without a pre-market approval process under other regimes, such as food or dietary supplements regimes. Any such list could be informed by reports of various domestic and international agencies, such as the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), Food and Drug Administration, Drug Enforcement Administration and reports published in scientific journals.

The problem of classifying “borderline products” is not new, and lessons can be learnt from demarcation between regimes for cosmetics, medicinal products, food and dietary supplements. For example, the quantity of active ingredient has been recognised as a criterion for distinguishing between food and medicine in EU case law, with products containing a low

quantity of the active substance considered a food rather than a medicine (Romero & Timmermans, 2009). The same criterion could be used to differentiate between psychoactive products and dietary supplements, with products containing low levels of active ingredients considered dietary supplements rather than psychoactive products. However, the very high potency of some NPS compounds means that limits would be very low and in a narrow range, and limits would need to be set on a substance-by-substance basis. A similar approach has been used in Belgium where a list of plants with corresponding limits on the active substance has been established to demarcate between dietary supplements and medicines (medicinal laws apply when limits are exceeded). For example, food supplements containing Ginkgo Biloba may not provide more than 21.6 mg of flavonol glycosides and 5.4 mg of terpene lactones daily according to the recommended advertised dosage ("Arrêté royal relatif à la fabrication et au commerce de denrées alimentaires composées ou contenant des plantes ou préparations de plantes (Mon. 21.XI.1997)," 1997).

The EU Medicinal Products Directive contains provisions that medicines regulations prevail in case of doubt ("Directive 2001/83/EC Of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use,"). For example, when a cosmetic product aimed to improve appearance also modifies physiological function of the body, under a "rule of doubt" it is considered to fall under medicinal laws (European Commission, no date). A similar categorical rule could be formulated to clarify the status of borderline products with psychoactive properties. For example, under a "rule of doubt" any product would be considered to fall under psychoactive regime if it produces "discernible impairment". A significant challenge would be to establish what constitutes "discernible impairment", and this might draw on existing standards of competency required to drive a motor vehicle or operate machinery. The judiciary are eventually tasked with assessing the appropriateness of classification rules and the categorisation of specific substances and products. They will make such decisions based on objectives of the regimes in question, not a pragmatic need to impose strict controls. For example, the European Court of Justice (ECJ) recently judged that synthetic cannabinoids consumed for psychoactive effects cannot be classified as medicines (joint cases C-358/13 and C-181/14) (European Court of Justice, 2014a). In their judgement the Court stated that while synthetic cannabinoids did fulfil the requirements of the definition of medicine according to its literal reading (i.e. 'modification of physiological function'); this was not sufficient in this instance. Having regard to the objective of the medicines regime, the ECJ interpreted that the modification needs to have beneficial effects for human

health. This example also illustrates that judicial disputes over the categorisation of products can lead to clearer definitions of the types of products that should sit in particular regime.

Legislation aimed at controlling new psychoactive substances inevitably includes exemptions of products and substances already covered in existing regimes, such as alcohol, tobacco, medicines and dietary supplements. An unintended consequence of these exemptions is they create an opportunity for 'creative compliance', i.e. the marketing of psychoactive products under the exempted regimes which impose lower regulatory controls and more lenient sanctions for non-compliance. In the New Zealand context this is particularly prevalent for herb-based products. For example, Lion's tail leaves and dried kava roots are available for purchase in legal high stores, labelled as natural health products. Following this strategy, a manufacturer linked to a leading legal high lobby group announced the launch of a herbal product "Posi+ivi+y", to be marketed in capsule form as a dietary supplement (Star Trust, 2015). On the other hand, failure to exempt certain classes of products can lead to inappropriate controls being imposed. For example, in contrast to laws passed in Australia and Ireland, the New Zealand definition of "psychoactive substance" does not exclude veterinary medicines, and consequently the passage of the PSA potentially outlawed the use of drugs with psychoactive effects in veterinary practice.

Given that some products with psychoactive effects will be covered by legislative regimes other than those purpose designed for psychoactive substances there is a need to establish robust safety standards to guard against product risks in exempted regimes. In New Zealand, the Natural Health and Supplementary Products Bill (New Zealand Parliament, 2015b) currently under parliamentary consideration, aims to strengthen regulatory controls over natural health products and dietary supplements. The Bill seeks to establish a pre-market notification system for these products, and introduce a list of allowed and prohibited ingredients. Online registration of a prospective product containing allowed ingredients would permit immediate market release, while products containing a new ingredient would need to undergo assessment by the regulator prior to being released on the market.

The disparity in penalties under the PSA and MODA places a much larger importance on forensic identification of the substance as part of policing, prosecution and court proceedings. In court proceedings, judges will deal with situations where either the PSA or MODA could potentially apply, depending on accounts of what offenders claimed they were selling/possessing, forensic analysis identifying the actual composition of compounds, and expert opinion on "psychoactivity" or "structural similarity" of a compound, if applicable. In personal possession cases, real-time testing of substances becomes essential to avoid unnecessary prosecutions. A

simple confirmatory test may be able to be developed and used to identify approved products once they appear on the market (Wilkins, 2014a), but there may be significant scientific challenges. Forensic testing takes time and is costly which leaves open the question of who should pay and whether funding limitations will lead to miscarriages of justice. Real-time differentiation between unapproved psychoactive products and drug analogues is not scientifically possible at present. This may eventually require revision of penalties for possessing substances under the PSA or MODA with the aim of standardising sanctions.

Finally, our analysis revealed issues with the definition of “psychoactivity” itself. Aspects of the definition such as the extent of psychoactive effect or the potential to cause dependence and other harms could add further clarity to the problem of demarcating between legal regimes. It has been suggested that narrowing the definition to synthetic compounds could reduce some problems relating to the broad scope of definition in the UK context (Stevens et al., 2015). Further investigation is needed into the legislative attempts to define NPS in various jurisdictions to establish the optimum elements of a definition which take into account the legal requirements of clear and unambiguous language as well as the current state of science.



## **Chapter 5: Issues with monitoring the safety of psychoactive products under a legal regulated market for new psychoactive substances (NPS) ('legal highs') in New Zealand**

This chapter explores how the PSA provisions on products worked during the interim regime. The investigation includes challenges with approving products, issues with monitoring their safety and the process of revoking interim product approvals if they subsequently caused harms.

Unlike Chapter 4, which relied on documentary and legal analysis, the findings presented in this chapter come from thematic analysis of interviews with key informants. In-depth interviews with key informants provided insights about how the legal and regulatory framework for interim approved products worked in practice; for example, why the legal criteria for interim approval of products turned out to be difficult to apply and what were the reasons for subsequent problems with the products.

The research paper comprising this chapter is published in *Drug and Alcohol Review*. Findings were also presented during the 10<sup>th</sup> Annual Conference of the International Society for the Study of Drug Policy in Sydney, Australia (16-18 May 2016).

Rychert, M., Wilkins, C. & Witten, K. (2017). Issues with monitoring the safety of psychoactive products under a legal regulated market for new psychoactive substances (NPS) ('legal highs') in New Zealand. *Drug and Alcohol Review*. Doi: 10.1111/dar.12507

## **Abstract**

**Introduction:** New Zealand's *Psychoactive Substances Act* (PSA) 2013 established the world's first regulated market for "low risk" psychoactive products ('legal highs'). Under an interim PSA regime 47 existing products were permitted to be continued to be sold.

**Aim:** To explore issues with the implementation of regulatory systems to monitor the safety of products on the legal market under the interim PSA regime.

**Methods:** Semi-structured interviews with 30 key stakeholders, including industry, government agency, health and drug service professionals were conducted, transcribed and analysed thematically.

**Results:** In retrospect stakeholders questioned the decision to approve strong synthetic cannabinoid (SC) smoking products, noting their health risks due to product formulation, inconsistent manufacturing practices and smoking as the means of administration. Industry actors claimed the decision to approve SC smokeable products prevented potentially safer products from gaining market share. The system for withdrawing approved products which were subsequently found to be harmful was criticised for the poor quality of data available, limited engagement with health professionals, and the slowness of product withdrawal. Many of the problems with the regime were attributed to the urgency under which the legal market under the interim PSA was established and implemented.

**Conclusions:** The selection of 'safer' products, implementation of the product monitoring system, and engagement with health professionals may have benefited from more time and resources. An incremental approach to establishing the new market may have made the regulatory management of the new regime more workable.

## Introduction

In July 2013, New Zealand established the world's first regulated legal market for recreational products containing new psychoactive substances (NPS, 'legal highs') with the passage of the *Psychoactive Substances Act* (PSA) 2013 (New Zealand Parliament, 2013a). Under the PSA, psychoactive products can gain government approval to be legally manufactured and sold provided product sponsors demonstrate through toxicology and clinical trials that their products cause no more than a "low risk" of harm to consumers (Wilkins, 2014a). This regulated market approach to NPS attracted considerable international attention as a pragmatic solution to end the ongoing problems with NPS (Brandt et al., 2014) and as a regulatory alternative to traditional prohibitive approaches (Bretteville-Jensen, 2014; Seddon, 2014).

At the time the PSA was passed, much of the regulation required for the regime to be made fully operational had not been developed, including the product testing standards. An interim regulatory regime was therefore established which allowed a limited number of products already on the market to continue to be sold until the full regulations were finalised (Wilkins, 2014b). The interim regime was deemed necessary to avoid the creation of a black market which could have emerged if all existing products had been immediately taken off the legal market (New Zealand Parliament, 2013b). The products approved for the interim regulated market were subject to new PSA restrictions relating to labelling, advertising and retail sales, including R18 restriction and that products could be sold only from licensed specialised retailers. Product packaging had to display the name and quantity of active ingredients, a health warning message, contact details for the manufacturer and the telephone number of the National Poisons Centre (New Zealand Parliament, 2013a). The interim PSA regime operated for 10 months until the Government brought it to an abrupt end in May 2014, following reports of social disruption around retail stores and health risks from products (MOH, 2014f).

While a number of international bodies have expressed interest in monitoring the implementation of the PSA (Commission on Narcotic Drugs, 2016; EMCDDA, 2015e; UK NPS Review Expert Panel, 2014; UNODC, 2013b), only a handful of publications have attempted to reflect on the challenges experienced during the interim PSA regime (Bell, 2015; Feilding & Singleton, 2016; Reuter & Pardo, 2017). This paper explores issues related to the approval of products for sale during the interim regulated market and the development and implementation of systems for ongoing monitoring of product safety. The issues identified will be of value to other countries interested in developing legal regimes for recreational drugs including NPS and traditional drugs like cannabis.

## **Background: Identifying products to receive interim approvals and developing the safety monitoring system**

Two legislative criteria included in the PSA were used to identify what products received interim approvals and were permitted to be sold on the interim market: (1) that the product had been on the market for at least three months prior to the passage of the PSA; and (2) that the product complied with the provisional “low risk” requirement, meaning it had not attracted any significant adverse event notifications (New Zealand Parliament, 2013a, 2013b). The Psychoactive Substances Regulatory Authority (PSRA), a new government agency established within the Ministry of Health (MOH) to oversee implementation of the PSA, was tasked with determining whether products met the required standards. Forty-seven products from 63 product applications were deemed to have met the criteria (75% approval rate) (Hannah, 2014). Forty of the approved products (85% of approvals) were synthetic cannabinoid (SC) smoking blends containing compounds such as AB-FUBINACA, PB-22, CL-2201, SGT-24 or 5F-ADBICA (Wilkins, 2014b). The interim PSA regime reduced the number of products available on the market from an estimated 300 products to 47 approved products (an 84% reduction).

The PSRA was given the power to revoke interim product approvals should information about harms associated with their use emerge (Wilkins, 2014b). To monitor the safety of interim approved products, the PSRA adapted a Poisons Severity Score (PSS) system, where health risk was measured by taking into account the severity and frequency of reported adverse events, and consumer exposure was estimated from sales data provided by the industry (Hermanns-Clausen et al., 2013; MOH, 2013b). Data on adverse events was intended to come from three sources: (i) calls from members of the public to the National Poisons Centre (NPC) and Drug and Alcohol Helpline; (ii) reports sent by medical professionals to the Pharmacovigilance Centre (CARM) and reports made by a subset of hospital emergency units; and (iii) notifications from product manufacturers who were legally obliged to report adverse incidents from their products (MOH, 2013b). Eleven products which were initially granted interim approval were subsequently withdrawn from the market during the 10 months of interim regime due to reports of adverse effects (Hannah, 2014); five in January 2014 (Wilkins, 2014b) and six in May 2014 (MOH, 2014b) (a week before the interim regime was ended). The 11 withdrawn products contained various concentrations of five SC compounds: AB-FUBINACA, PB-22, PB22-5F, CL-2201 and CP-55,244, some of which have since been banned in other countries (Drug Enforcement Administration Department of Justice, 2014; *German Federal Narcotics Act*, 2014).

Another regulatory instrument to control the quality of products, the *Code of Manufacturing Practice*, was finalised by the PSRA in January 2014, i.e. six months into the interim regime (MOH, 2014e). It came into force immediately and allowed the PSRA to monitor the quality of products on the interim market. The introduction of the *Code* resulted in suspension of all 10 interim licenses to manufacture (MOH, 2014f). However, the process of further auditing required to revoke interim licenses to manufacture was interrupted by the revoking of all remaining interim product approvals by the parliamentary amendment to the PSA.

## Methods

To inform our initial understanding of the issues of concern with the PSA we completed content analysis of 114 public submissions to the Psychoactive Substances Bill ("Submissions to the Psychoactive Substances Bill 2013,"). We also reviewed six sets of parliamentary readings on the Psychoactive Substances Bill and the Psychoactive Substances Amendment Bill (New Zealand Parliament, 2013b, 2014b) and four MOH Regulatory Impact Statements (MOH, 2011a, 2012, 2014f, 2014g). This document analysis allowed us to identify key issues of concern to be explored in the interviews and identify a number of stakeholders to be interviewed.

Thirty one-on-one semi-structured interviews were conducted with stakeholders who were involved and/or affected by the implementation of PSA regime. They included politicians (4); civil servants (4); industry-related actors (5) including a legal high entrepreneur, a chemist and retailers; health sector professionals (4) including emergency department and detoxification unit doctors; toxicologists (2); NGO and drug community services staff (5); local body representatives (2); health and drug policy academics (2); and law enforcement personnel (2). An interview guide was used to explore participants' experiences with the process of implementing the PSA. As part of the interview participants were asked a series of questions about the products sold during the interim PSA regime and the systems used to monitor and withdraw products. Interviews were conducted from October 2015 to February 2016. Twenty-eight interviews were conducted face-to-face, one by phone and one using Skype video chat. The interview times ranged from 22 to 124 minutes, with a mean time of 67 minutes. All interviews were conducted, recorded and transcribed by the first author. Thematic analysis of interview transcripts was completed by inductive and deductive coding (with the interview guide as a coding framework) (Braun & Clarke, 2006; Patton, 2015). A qualitative description approach, characterised by low-inference interpretation (Sandelowski, 2000), was used to analyse data and report findings.

## Results

### PSA criteria used to select products for interim approval

Most participants were unfamiliar with the two PSA legislative criteria used to approve products for the interim regime. Among the better informed stakeholders were industry and policy actors who tended to view the approval criteria as reasonable, given the time pressure to choose products for the interim market:

*“It's hard to know what else you [could] do in that interim space” (P7, civil servant)*

*“You know, everything was happening so quickly that I can understand why [these criteria were used]” (P29, industry)*

Some participants questioned the rigour of the selection criteria. Several alternative methods to select products for the interim market were suggested, primarily *“some other pre-market safety screening”* (P21, industry actor) or *“some sort of small trial”* (P8, health professionals). One industry actor suggested that more attention should have been paid to the quality control of products when they were first granted interim approvals:

*“That 3 months period of no complaints - I've always felt that it wasn't a smart way to go about it. I thought what they should have done would be to take all the products that had applied for it, and purchase them anonymously from retailers and then analyse whether what they say is in it per gram is actually in it.” (P29, industry)*

A couple of participants commented that the anticipated full PSA regime, with good manufacturing practice (GMP) standards modelled on regulations for the pharmaceutical sector, was tailored to regulate products with a dose-control delivery system such as pills, capsules, or inhalers. These participants thought that the interim approval process should have taken these principles into account and allowed only products with controlled delivery systems to stay on the interim market, essentially resulting in the banning of all synthetic cannabinoid smoking blends.

### Applying the PSA criteria for products in practice

Regulatory personnel tasked with granting interim product approvals identified difficulties with applying the two PSA legislative criteria to real-world situations. First, they identified that the evidence of harms associated with products on the market was limited, because there was

no comprehensive system for monitoring harms associated with specific product brands before the PSA came into effect:

*“In reality there was still little data in that space. In 99 per cent of the time, you know, most of the applications for the interim licenses had no outstanding adverse reactions against them.”* (P7, civil servant)

Second, there were difficulties with obtaining reliable information from the industry to support the claim that the products had been on the market for a 3-month period before the law was passed:

*“We had to rely on good faith. (...) We had issues, where it might be a brand new product but they declared that it's over 3 months. But sometimes it's hard to know. And sometimes it's because we get another product sponsor who comes back and says "I see you've licensed this one, but this product has only arrived on the market, it hasn't been there for 3 months".* (P15, civil servant)

### **Perceived safety of interim approved products**

The reduction in the number of products available on the market following passage of the PSA was overwhelmingly viewed as a positive outcome of regulation, but a couple of participants thought the absolute number of products remaining on the market (47) was higher than they had expected for the regulated market.

When asked about their opinion on the safety of interim approved products, many participants commented that significant harms were associated with many of them. As illustrated in the following quote, health professionals focused on the harmfulness of synthetic cannabinoids in general, i.e. their addictive potential and the risk of respiratory disease due to smoking:

*“The problem is, particularly with synthetic cannabis, that they are very potent. So basically it truncates someone's six months of normal cannabis smoking into two weeks. There's nothing special about the drug itself... it's just a straight out potency. (...) And we've been having ridiculous stories, people having to wake up at 2 o'clock in the morning to smoke some stuff because they were hooked.”*(P8, health professional)

Several industry actors observed that most interim approved products contained compounds which were third or fourth generation of synthetic cannabinoids, which they thought were more

harmful than the earlier compounds that had been previously banned from the market. One participant went as far as to say:

*“The whole thing [interim regime] from the start was doomed. Because the products that were deemed to be low risk were the strongest synthetic cannabis products that have ever been sold in this country. You know, there was no way by anyone's standards that they were low risk, that was just a ludicrous thing to say.”* (P20, industry)

In addition to comments about the safety of active ingredients, some participants focused on the safety implications of variation in strength of products from batch to batch. These participants held views consistent with the comments such as that the interim approved products *“were quite harmful, depending on how well prepared the batch was or not”* (P1, drug community services staff), manufacturing was of *“low quality”* (P7, civil servant) and the quality control during the interim regime was *“random”* (P1, drug community services staff).

Many participants attempted to contextualise harms from interim approved products in the wider context of legal psychoactives, and commented that harms from approved products remained lower than harms from alcohol during the interim regime. When asked about the interim approved products other than smoking synthetic cannabinoid blends, such as genuinely natural products (e.g. a blend of kava, citrus aurantium and caffeine) or products in a pill form (e.g. “4:20 pill” containing synthetic cannabinoid SGT-42), most participants were unaware of these products, and the industry actors commented that they were not popular enough to attract customers in view of competition from stronger smoking SC blends that had been allowed to remain on the market.

### **Quality control of interim products and its unintended consequences**

While no safety testing of products was required under the interim regime, the *Code of Manufacturing Practice* required all manufacturers to ensure that *“products were manufactured to a consistent standard and were free from impurities”* (P20, industry). Controlling the quality of products during the interim regime proved challenging. Industry actors and laboratory personnel believed that technical issues impeded the implementation of new quality tests:

*“We were struggling with obtaining high quality, high purity reference substances for some of these things [compounds], because many of them were very new. You also have a problem of determination of variable recovery from material such as plant material, you've got to go through extraction process where you can get interferences (...). So it's*

*quite problematic. My feeling was we were struggling with actually implementing those levels of testing for consistency at that point. (P30, toxicologist)*

One industry actor also mentioned unintended consequences of new product quality tests. Since the manufacturers of interim approved products were required to demonstrate that the products contained the exact amount of active ingredients detailed on the package, as described below, some manufacturers claimed they had to increase product strength:

*“When the first round of quality control testing came in, it turned out that [name of product] which was licensed to contain 5mg of active per gram, actually contained only 2.7mg/g (...). Even though there were already some complaints that this product was verging on being too strong, though not to the Poisons Centre, we were sternly instructed that we had better get future batches up to the stated 5mg/g level or risk losing our license, even though this would have made the product nearly twice as strong!” (P20, industry)*

### **Availability of data to monitor the safety of interim approved products**

Participants were asked about their experiences with the system developed to monitor product safety under the interim PSA regime. As illustrated below, health professionals interviewed were concerned about underreporting of adverse events through CARM due to the lack of awareness among medical personnel about how and where to report poisonings and other adverse reaction cases:

*“It was the first time ever that they [CARM] were asked to monitor adverse reactions from substances that are not prescribed. So I guess it wasn't the usual process. In that respect, a lot of health professions - it wouldn't be their first thought to make a notification to CARM.” (P5, health professional)*

*“[When the interim regime was coming to an end] we sent out a survey to all the emergency physicians in the country, we got pretty high response rate, 53 responses which is about 50% or something. All of them said they'd seen recreational highs. (...) And see, this was stunning: “do you know how to report complications related to psychoactive substances?” and 70% didn't even know. So they didn't even know that there was a reporting system through CARM. (P8, health professional)*

A couple of medical professionals were concerned that a large volume of data on adverse events from products were not taken into consideration when regulatory decisions were made,

because the existing hospital admissions dataset was not tailored to collect data on synthetic cannabinoids and specific products, and the codes were not applied consistently across different District Health Boards.

Drug community services staff and some NGO representatives working with communities also commented that users who experienced adverse reactions and their families were unsure about where to report experiences of adverse events:

*“People who did the reporting didn’t seem to know where to report to. There were three different numbers that you could possibly call. There was National Poisons Centre, there was a kind of Alcohol and Drug Helpline...a number of entering points that weren’t really linked up very well. And the people weren’t really quite sure about which number they should call. It was confusing to our staff who works in the field then for the general public that would have been even harder.”* (P1, drug community services staff)

### **Quality of data on adverse events**

Due to the limited volume of reports from medical professionals, the PSRA mostly relied on data from the NPC. A number of limitations with the NPC data were identified during the interviews, including the fact that harms were voluntarily self-reported by members of the public (free telephone call ins), and the influence of dosage, poly-drug use, and pre-existing mental health disorders were not accounted for. Some industry actors suggested that fake calls to NPC could have been made by market competitors reporting problems with other producers’ products.

*“Most of the people who phoned up didn’t know what the fxxx they had [taken]. They’d say they had Spice. But Spice at that point hadn’t been on the market for 6 months! So it became genericised. (...) Then there were people calling up “yeah, hey, is this really good for sex?” and in brackets: “girls laughing in background”. The quality of information was really poor.”* (P27, drug policy researcher)

*“It didn’t matter what else you took, all of the side effects were attributed to synthetic cannabinoid, rather than a potential polydrug abuse, or alcohol and party pills, or psychoactive abuse. Because it was impossible to separate those things. And so... in some extent, it’s possible that products were penalised because of what else people were doing. But then... but that’s part of the deal”.* (P7, civil servant)

From the regulatory perspective, the process of identifying the harms attributed to a particular product was described as time-consuming and labour intensive.

*“What we had to do is, line by line, we had to go through all records, and we had to try to eliminate, try to distinguish between the real calls, which seemed like evidence of real harm, versus those that are just ringing up... You know, people were just ringing up and saying “this is good sxxt, where can I get some more?” - that's a call. But we can't count it as a harm. So we had to try and make groups, of potentially harmful ones. (P15, civil servant)*

Participants with insider knowledge of the monitoring system commented on increasing availability and quality of data as the interim regime progressed, with more consumers able to recall the name of a particular product used, more systematic reports coming from the emergency departments, and increased compliance of businesses with the requirement to report volume of sales.

### **Consistency of product withdrawal decisions**

Interviewees were divided in their opinions on the consistency of product withdrawal decisions. Those involved in the process viewed it as professional, given the limited availability and quality of data. *“They set up the algorithm and stuck to the algorithm, and I respect that”* – was one participant’s assessment (P26, toxicologist). However, a number of limitations were also identified. Some participants criticised the system for its focus on products rather than substances. One participant described how this approach resulted in, what s/he called, *“absurd outcomes”*:

*“For instance, one of the [product identified] got withdrawn because of convulsions and the weird fugue state, but then other products containing the same active ingredient at a higher concentration were allowed to stay on the market, because those ones happened not to have had complaints made about them yet. (...) if you ban the product containing 20 milligrams and you allow the product containing 50 milligrams to stay on the market, that's just ridiculous, there's no consistency behind that. It was completely arbitrary.” (P20, industry)*

## **Speed of withdrawing harmful products from the market**

Another criticism of the system for monitoring safety of products available on the interim regulated market focused on the speed of withdrawing harmful products. Some participants thought that products causing problems were withdrawn too slowly, given concerns in the community:

*“That was the judgement we made, that there was enough safeguards in the interim period to remove any of the interim approved ones off the market. (...) You know: 7 days, gone! And we all knew there were products that had problems under this interim period: calls to the poisons centre, the treatment people were saying... I think there was enough indication that some of those early approved products were causing problems. And they didn't act. And they could have acted.”* (P9, NGO staff)

From the regulatory perspective, the litigant approach of the industry and limited resources of the regulator were thought to be some of the reasons for the slow responsiveness of the system for withdrawing products:

*“To withdraw a product, you can't just say "oh, I withdraw", you need to have a reason for doing it, a documented reason, with scientific, medical and the legal perspective. Could you do that in a week? When you have staff busy looking at other products, retail licenses, trying to get the Code of Manufacturing Practice done. (...) Some approvals, we revoked and we ended up in court. The industry was very litigant in its approach, the way they operate. So not only did we have the clinical assessment, scientific assessment, the regulatory assessment, we also had a bunch of lawyers around to work that stuff out as well.”* (P14, civil servant)

## **Discussion and Conclusions**

The ending of the interim PSA regime in New Zealand, and the issues and challenges experienced provide a number of important findings for other countries considering regulatory approaches to NPS or other psychoactive drugs, including cannabis.

Participants in this study identified issues with the selection of ‘safer’ products for the interim PSA regime and challenges with the ongoing monitoring of product safety. Some participants questioned the number of products allowed to stay on the interim market, suggesting fewer products may have made the management and monitoring of products more workable. Commentators on the cannabis regimes in the United States have noted other public health

benefits to cautiously opening up the new market, including reducing the risk of rampant commercialisation in the early stages (Pacula, Kilmer, Wagenaar, Chaloupka, & Caulkins, 2014). The subsequent issues with the products approved for the interim PSA regime suggest the criteria within the PSA for interim approval may have been too liberal. Indeed, the time period defined in the PSA during which a product was required to have been on the market and *not* received any reports of adverse effects was actually reduced during the Parliamentary Select Committee stage, down from six to three months (New Zealand Health Committee, 2013). Second, interim product approvals relied on data about adverse events from specific products which was largely not available at the time the legal market under the interim PSA regime was established.

Much criticism of the process of selecting products focused on the fact that most of the products which received approvals were strong synthetic cannabinoids in a smokeable form. A number of New Zealand studies have identified serious health problems and issues of dependency related to the synthetic cannabinoids used during the interim PSA regime (Glue et al., 2016; Glue et al., 2015; Macfarlane & Christie, 2015; Wilkins, Prasad, Wong, et al., 2016). There are also well known health risks associated with smoking (Strang et al., 1998; US Department of Health and Human Services, 2014). In this study industry actors claimed that approval of a large number of smokeable SC blends prevented potentially safer products (e.g. in a pill form) from gaining any market share and regulatory personnel also questioned whether any smokeable herb-based product which is burnt could pass the “low risk” threshold and meet standards around manufacturing and quality control under the full PSA regime. This casts doubt on whether approval of smokeable products for the interim regime was justified.

An important issue which arose during the interim regime was the speed and effectiveness of the system used to monitor the safety of products and withdraw problematic products. The challenge is to set up a system which is highly-responsive and able to remove unsafe products from the market as quickly as possible (Ghosh et al., 2015). In New Zealand, finding a balance between the safety of consumers and the industry’s legal economic rights proved challenging, illustrating the need for careful thought as to what type and amount of evidence is sufficient to withdraw a product from the market. This is important because administrative decisions to withdraw or decline approval of any product will be legally challenged by the industry if they are based on evidence of harm which is not specified in the regulatory framework. Experience with the alcohol and tobacco sectors over many decades has demonstrated the willingness of the industry to actively oppose regulatory restrictions on products and marketing through the courts

(Babor, Caetano, et al., 2010).

Building an effective monitoring system for new types of psychoactive products requires resources and on-going engagement with health professionals who are expected to report adverse effects. Some participants in this study reported that this type of engagement was limited during the interim PSA regime which reduced the amount of data available on adverse events. Effective coordination between different entry points and tailoring the existing administrative data sets and processes to capture adverse events also proved challenging. Some relevant data was not taken into account at all, due to the fact that the existing system for recording reasons for hospitalisations and visits to Emergency Departments (ED), i.e. *International Classification of Diseases* (ICD) lacks codes specific to events involving synthetic cannabinoids. As a result, codes were applied inconsistently across different EDs and records did not refer to specific synthetic cannabinoid *products*, as required to make regulatory decisions under the PSA. The lack of cannabis specific-codes and their inconsistent application have also been identified as challenges in monitoring health impacts from the legal cannabis market in Colorado (Berger, 2016; Ghosh et al., 2015).

Many of the problems identified with the interim PSA by participants in this study were attributed to the time pressure under which framework for the interim PSA regime was developed. Since the ending of the interim regime in May 2014, the work on developing regulations has continued and the regime is now ready to receive “low risk” product applications under the full PSA framework. No product applications have been made to date (as of September 2016). In the event of products being approved, the findings from this paper suggest the need for more engagement with health professionals and enhancement of systems to ensure products which produce adverse effects are removed from the market in a timely fashion.

## **Chapter 6: “Lost in translation”: issues with the establishment of a legal market for ‘low risk’ psychoactive products (‘legal highs’) in New Zealand**

Chapter 6 further investigates issues with implementation of the PSA under the transitional provisions. It investigates challenges related to: (1) establishing and monitoring the regulated retail network for the products; and (2) communicating the policy to stakeholders and the public. Further, it probes into the issue of the availability of resources during the interim regime, which was signalled in the previous chapter.

These issues were explored by thematically analysing data from key informant interviews. The findings were then contextualised within the broader drug reform context, by discussing the challenges identified in New Zealand with reference to recent cannabis law reforms implemented in Uruguay and US states of Colorado and Washington where regulated legal markets for cannabis have recently been established.

The research paper comprising this chapter is published in *Drugs: Education, Prevention & Policy*. The findings also contributed to an article about the PSA and its implementation which I wrote for the Information Centre for Drugs and Drug Addiction in Poland (published in English and Polish) (see English version of the article in Appendix I).

Rychert, M., Wilkins, C. & Witten, K. (2017). "Lost in translation": issues with the establishment of a legal market for 'low risk' psychoactive products ('legal highs') in New Zealand. *Drugs: Education, Prevention & Policy*.

## **Abstract**

**Introduction:** New Zealand's *Psychoactive Substances Act* (PSA) 2013 established the world's first regulated legal market for "low risk" psychoactive products.

**Aim:** To explore challenges in relation to regulating the retail environment and public communication of the new policy.

**Methods:** Semi-structured interviews with 30 key informants (KI) from the industry, government, health and NGO sectors were conducted, transcribed and analysed thematically.

**Results:** KI overwhelmingly supported the new PSA retail restrictions, but expressed frustration about how the new regulations were managed. They questioned the effectiveness of communicating the policy to the public and media, enforcement of regulations around licensed retailers, engagement with stakeholders in local communities, and the speed of developing regulations for the full regime. Many KI pointed out the reduction in the number of shops concentrated demand which increased social disruption and negative media feedback. The absence of price controls and drug education were identified as gaps in the new regime.

**Conclusion:** Issues with the interim PSA regime highlight the significant challenges of implementing frameworks for regulated drug markets. Many issues were attributed to unrealistic timeframes, resource constraints and insufficient planning. An important task is effectively communicating the new policy to the public, engaging with local stakeholders and educating users.

## Introduction

In July 2013, the New Zealand Parliament passed the *Psychoactive Substances Act* (PSA), which established the world's first legal framework for a regulated legal market for new psychoactive substances (NPS) ('legal highs') (New Zealand Parliament, 2013a). Under the PSA, sponsors of psychoactive products can receive government approval to legally manufacture and sell their products, provided they demonstrate through toxicology and clinical trials that their products pose no more than a "low risk" of harm to consumers (Wilkins, 2014a). The central objectives of the PSA are to regulate the NPS market and "minimise harm to individuals who use psychoactive substances" (s.3, PSA) by establishing a regulatory framework to identify "low risk" psychoactive products, provide consumers with information about the safety, contents, dose, and potency of products legally available, and regulate the availability of products by establishing retail restrictions such as purchase age and place of sale control (MOH, 2012). Under the PSA, the sale and possession of products which have not received regulatory approval is prohibited by default (Rychert & Wilkins, 2016b). This regulatory approach to NPS sits in stark contrast to traditional prohibitive drug policies and received considerable international attention as a pragmatic solution to ongoing problems with NPS which could potentially be implemented in other countries (Brandt et al., 2014; Bretteville-Jensen, 2014; Seddon, 2014; UK NPS Review Expert Panel, 2014).

At the time the PSA was passed much of the regulatory framework for the new regime had not been developed, including the specific tests required to prove products were "low risk". Consequently, an 'interim' PSA regulatory regime was established, under which a limited number of NPS products which had been available on the market before the PSA and had not caused any major health concerns were allowed to continue to be sold until the regulations were finalised (Wilkins, 2014b). The new interim PSA regulated regime reduced the number of products on the market from an estimated 300 products pre-PSA to 47 approved ones, and the number of retail outlets from around 4,000 to 153 specialised stores (Hannah, 2014). The PSA also imposed new restrictions on the age of purchase (R18), labelling (including obligatory health warning and disclosure of ingredients on the packaging) and advertising of products (advertising limited to place of sale). The interim market was brought to an abrupt end in May 2014 following ongoing reports of adverse effects from products and social disruption around licensed retail outlets (MOH, 2014f).

A number of authorities around the world expressed an interest in monitoring progress with the implementation of the PSA (Commission on Narcotic Drugs, 2016; EMCDDA, 2015e; UK NPS

Review Expert Panel, 2014; UNODC, 2013b), but, to date, only a handful of articles have attempted to reflect on the challenges experienced during the interim PSA regime (Bell, 2015; Feilding & Singleton, 2016; Reuter & Pardo, 2017; Wilkins, 2014b). This paper explores the challenges experienced during the interim PSA regime related to establishing a regulated retail environment, the role local communities played in this process, and the issues with communicating the new policy approach to the public and media. The findings will be of value to other countries interested in developing legal regimes for recreational drugs, including NPS and traditional drugs like cannabis.

### **Background: interim retail framework and the role of local communities in the PSA**

Under the PSA, approved “low risk” products can be sold only from specialised licensed retail outlets and to customers 18 years and older. No food or alcohol can be sold from the licensed retail premises. The PSA explicitly bans the sale of approved products from supermarkets, petrol stations, local convenience stores or alcohol outlets (New Zealand Parliament, 2013a).

Under the interim PSA regime, retailers who had been selling ‘legal highs’ for at least four weeks prior to the passage of the PSA and declared compliance with the new PSA retail restrictions were eligible to receive retail licenses to sell products on the interim market. The interim PSA market was expected to operate for no more than six months, by which time the full PSA regime would be available (MOH, 2014f) and all retailers and product sponsors would need to apply for full PSA licenses. The Psychoactive Substances Regulatory Authority (PSRA), a new government agency established to oversee the implementation of the PSA, issued 153 retail licenses under the interim regime; resulting in a 95% reduction in the number of outlets selling NPS products compared to the pre-PSA, when an estimated 4,000 unlicensed shops, mostly local convenience stores, sold NPS products.

In addition to restrictions on the type of premises allowed to sell psychoactive products, the PSA also granted local government authorities the power to develop Local Approved Product Policies (LAPP) which can impose further restrictions on the location of retail outlets in their local districts. These provisions were added to the Psychoactive Substances Bill at the Select Committee stage following public submissions raising the issue (New Zealand Health Committee, 2013). The PSA specifies that local councils can: (1) define broad areas where outlets can be located, (2) limit the density of outlets, and (3) define minimum distance from sensitive sites, such as schools, churches or addiction treatment facilities. By the end of the interim

regime, only five out of 71 local councils had developed their LAPPs (L. Anderson, 2014). As of 2016, around half of the local authorities in New Zealand have adopted LAPPs (PSRA, 2015b), with most of them aiming to restrict the location of licensed retailers to city centres and away from residential suburbs.

During the interim regime 13 interim retail licenses were suspended (10) or cancelled (3) for non-compliance with PSA retail requirements (e.g. no sales of food and alcohol from the same premises) or due to new restrictions on location of retailers established by LAPPs (PSRA, 2013, 2014b, 2014d).

## **Methods**

A range of formative work was completed to inform the interview guide and identify stakeholders to be interviewed, including content analysis of 114 public submissions to the Psychoactive Substances Bill ("Submissions to the Psychoactive Substances Bill 2013,"), review of six sets of parliamentary readings of the Psychoactive Substances Bill and the Psychoactive Substances Amendment Bill (New Zealand Parliament, 2013b, 2014b), and review of four MOH Regulatory Impact Statements (MOH, 2011a, 2012, 2014f, 2014g).

One-on-one semi-structured interviews were subsequently conducted with 30 key informants (KI) who were involved and/or affected by the implementation of the interim PSA regime. These included politicians (4), civil servants (4), industry-related actors (5) including a leading legal high entrepreneur, a chemist and retailers, health sector professionals (4) including emergency department and detoxification unit doctors, toxicologists (2), NGO and drug community services staff (5), local body representatives (2), health and drug policy academics (2), and law enforcement personnel (2). A total of 42 stakeholders were invited to participate in the study: four refused, five did not respond, and three agreed to participate but were not available for an interview in the interview timeframe.

An interview guide was used to explore participants' experiences with implementation of the PSA, including development of the retail environment and communication of the new policy approach to the public and media. The interview guide consisted of general questions and a set of specific questions tailored to different stakeholders depending on their role in the regime. Interviews were conducted from October 2015 to February 2016. Twenty-eight interviews were conducted face-to-face, one by phone and one by Skype video conference. Interview times ranged from 22 to 124 minutes, with a mean duration of 67 minutes. All interviews were conducted, recorded and transcribed by the first author. The thematic analysis of interview data

combined inductive and deductive approaches. The topics covered in interview guide provided the initial (deductive) coding framework for sorting data thematically (Braun & Clarke, 2006; Patton, 2015). The second author coded three randomly selected interviews and through discussion between the first and second authors, emergent themes were identified inductively and the themes finalised. A qualitative description approach, characterised by low-inference interpretation (Sandelowski, 2000), was used to analyse data and report findings. The project was evaluated as low risk and registered with the Massey University Human Subjects Ethics Committee.

## Results

### Licensing retailers for the interim PSA market

The participants were overwhelmingly in favour of the new retail restrictions imposed by the PSA. They were particularly supportive of the reduction in the number of retail outlets selling NPS.

However, several key informants identified challenges in establishing and monitoring the new retail environment. First, they noted that retailers were able to avoid certain regulations through 'creative compliance':

*There was a way of getting around some of the restrictions. So for example, you couldn't sell from the premises that sold alcohol, so what you do is you create a shop within a shop. So you say: "well, we're not selling it from the alcohol shop. This shop here is actually a different shop, it's even got a different business name", even though it was literally next door to the counter. Things like this. (KI-16, local authority)*

Second, a couple of key informants directly involved in the process of licensing retailers noted that the retail licensing system was operated from Wellington (the capital of New Zealand) by a central government agency (i.e. the PSRA), while enforcement through visits to retailers was delegated to local health authorities. This was perceived to complicate the process of assessing compliance:

*And, of course we're sitting in Wellington [capital city], we don't have eyes out there. We had to work with the public health people [i.e. health enforcement officers], who had to go and visit those places. (...) People [retail applicants] were (...) withholding information, or rebuilding [premises] so it becomes a different building, which means it couldn't*

*qualify [for an interim license], but then somebody goes to visit and it looks compliant.*  
(KI-15, civil servant)

### **Problems with interim licensed outlets**

A number of key informants made a distinction between what they referred to as 'good' (KI-9, NGO) or 'responsible' retailers (KI-13, law enforcement) and 'bad' (KI-4, industry actor) or 'dodgy' retailers (KI-16, local body). The former were perceived and described as mostly located in city centres, with a limited product range and consistent R18 checks, and the latter as located in poorer neighbourhoods and targeting customers from low socioeconomic backgrounds.

Retail behaviours identified as problematic included discounting product prices and keeping stores open late at night. Several key informants pointed out that the lack of price control provisions in the PSA and lack of restrictions around retail opening hours facilitated this behaviour.

*I know that some of the places in [name of city] were offering to sell with discounts. (...) We had one or two places where, if people didn't have any money, they [retailers] would offer credit: "you take these two packets and then when your benefit [social welfare payment] comes in on Thursday, give me the money back.* (KI-25, health professional)

*It was ridiculous that you couldn't limit the hours of selling the products. We had a 24-hours shop on [street name]. 24-freaking-hours. So when all bars and pubs were closed you could just go and purchase from this shop. And that shop, man... the amount of trouble that happened around that particular shop was shocking.* (KI-1, drug community services)

Some key informants questioned the on-going enforcement of the PSA retail provisions during the interim regime (KI-16, local body; KI-27, drug policy researcher; KI-29, industry). One key informant described his visit to a local interim licensed retailer and questioned the effectiveness and frequency of random audits monitoring retailers' compliance:

*I went to the shop down in lower [street name], ironically just down the road from the needle exchange. I went in there, and I saw these packets in the glass case. And I talked to the guy. (...) The guy couldn't speak English. So it would be quite difficult for him to ask you for your ID, you know. (...) They didn't regulate. I mean, they had regulations but they didn't police their regulations.* (KI-27, drug policy researcher).

## The 'bottleneck effect'

Despite overwhelming support for the reduction in the number of retail outlets after passage of the PSA, many key informants talked about the unintended consequences of these restrictions, i.e. concentration of demand for products to a reduced number of retail outlets. One key informant referred to this phenomenon as a 'bottleneck effect' (KI-4, industry). This was perceived to increase the visibility of stores in local communities:

*(...) and what that meant was that demand which had been less visible, was all of a sudden concentrated in a much smaller number of areas. I think that made the use of psychoactive substances much more visible to a much wider part of society. And they were understandably bothered. And they saw it as being a consequence of the Bill [PSA] rather than something that was invisible to them previously. (KI-19, politician)*

## Backlash from local communities

Many key informants identified that the backlash from local communities following passage of the PSA was the main challenge during the interim regime. Community opposition to the interim market was attributed to the 'bottleneck effect' and the wider problem of limited understanding of the policy rationale in the community:

*I had a public meeting in [poor neighbourhood district], and honestly I was lucky to get out of there alive. (...) that was predominantly Maori, Pacific Islanders, and lower socioeconomic audience there, and... I would summarise that as: "we have enough problems; our young people grow up facing enough challenges." A lot of people thought that the legislation legalised something that was previously illegal. There was a lack of understanding. (KI-10, politician)*

Several key informants attributed this limited understanding to the lack of clear public communication of the new policy approach. A couple of them went as far as to say that '*people were really surprised*' (KI-10, politician; KI-6, health manager) when psychoactive products remained on the market after the passage of the PSA, because the common understanding was that the PSA was about to ban all legal highs. Some key informants thought that the initial public support for regulation of psychoactive products was overestimated. '*More work needs to be done to get the society accept this kind of regime [a regulatory approach]*' – was one participant's comment (KI-14, civil servant). They also commented that the lack of a broader debate around drug policy when the PSA was proposed made the interim regime particularly

vulnerable to community concerns. In this context, the lack of education around recreational drug use was identified as a gap in the policy:

*Nobody really talked about it [drug taking], as an action, as a behaviour. You can't talk about drug taking. Just in a negative way. You can't educate people. There's no provision for education within the Act as far as I can see. (KI-27, drug policy researcher)*

### **Slowness in implementation of LAPPs**

Key informants involved in the process of developing local policies (LAPPs) were asked about the reasons for the slow response from local governments in developing LAPPs. These stakeholders indicated that LAPPs were not given priority because: (1) the process of developing LAPPs was expensive and time-consuming, particularly for smaller councils; (2) local authorities were unhappy about the lack of specific consultation with them when the PSA Bill was being developed, and consequently viewed LAPPs as imposed on them by the central government, and (3) LAPPs were not compulsory under the PSA and were not seen as essential by councils:

*One of the problems with the LAPP was that it was thrown in, I think, at the second reading [of the PSA in Parliament], and it wasn't particularly well thought through, I think. 'Cause in theory it had no teeth to it. In the legislation, it said that the [Central Government] Regulatory Authority wasn't required to conform to it. The [Central Government] Regulatory Authority had to take it into account, but it wasn't bound by it. So the LAPP wasn't a legislative instrument that says "you cannot have a shop in this place", it just says "we don't want a shop in this place", and the [Central Government] Authority could take it into account when making decisions. (KI-16, local body)*

Some participants thought that councils viewed the regulation of psychoactive substances under the PSA as 'a policy issue that they didn't want to be in, they didn't want to know about' (KI-24, local body), in light of the opposition of local communities to retail outlets. A couple of participants described this attitude as 'NIMBYism' (i.e. acronym for 'Not In My Back Yard', which refers to resisting unwanted change in a person's neighbourhood):

*The Mayor of [city] popped in saying "We don't want any on this side of the [region]". And I said: "Yes? Is that what you want? You can do it according to the law, you can do it, but it will be on that side of the [region], and you won't have any power to enforce it because it will be illegal and underground. And if that's what you want..." [S/he] said: "I*

*don't care about that. I just don't want any of these shops in my district". (KI-14, civil servant)*

### **Opposition from local councils**

Key informants identified that some councils demonstrated their opposition to the interim PSA regime by implementing LAPPs which essentially prevented the operation of any retail outlets in their districts. A number of key informants referred to the LAPP developed in the city of Hamilton, where a restrictive policy was put in place by specifying that bus stops fall under the 'sensitive site' distance restriction, based on the understanding that children would be present, and thus severely reducing the number of places where outlets could be located. A couple of interviewees thought that the vague language of the PSA provisions around LAPP enabled the councils to implement *de facto* prohibition:

*I think that some of the councils used quite sophisticated tactics how they could utilise the language in which the legislation was framed (...) one of the ideas in the legislation which was undefined was a "sensitive site", and so Hamilton specifically defined bus stops as sensitive sites. (...) I was also interested in the councils that went for joint up policies... because that was another option they could do. One that I recall is the New Plymouth district and Stratford District that was a case where you had a de facto prohibition, because basically the policy only allows sale in New Plymouth. And that's another way of getting around it. (KI-24, local body)*

### **Engagement with the media and public opinion**

Two key actors responsible for defining the public debate around the PSA were identified during our interviews: (1) the Government and the Ministry of Health (MOH) and (2) the media. Participants acknowledged some efforts from the former to inform the public about the new regulatory approach, such as press releases and media appearances. However, some key informants viewed the public communication efforts as ineffective:

*I met with [regulatory personnel name] and said: "we need to look into our communications". And [s/he] said "No, no, it's all right, we've updated our website". And I was thinking [laughs]: "No, no, you don't get it! Updating your website and having a proactive media strategy are two different things. (KI-9, NGO)*

Most key informants saw the public debate as being led by the mass media. 'If you create a vacuum, that vacuum is filled by silly things' – was one key informant's comment (KI-9, NGO).

Many key informants interviewed, including politicians, regulatory personnel, industry actors, health professionals, and researchers had direct personal contact with the media professionals during the interim regime. A *'productive discussion'* was how one key informant assessed his personal experience with media (KI-28, psychologist). However, most key informants perceived that the media focused on sensational stories featuring negative health and social problems:

*The media was, correctly or incorrectly, identifying stories where people were addicted, and they were defining the debate.* (KI-13, law enforcement)

Some key informants went as far as to say that the media reporting was *'unbalanced'* (KI-27, drug policy researcher), *'hostile'* (KI-12, politician), *'vicious'* (KI-4, industry) or uninterested in reporting positive news:

*You know, there was a lot of media coverage around some of this stuff, which, although we've been saying "let's take the ED admissions and see what alcohol is looking like", and no, they didn't want to do that. They wanted to focus on the story. The media has made its mind up, that it was a bad thing.* (KI-7, civil servant)

*[News host name] had been running his stories for over a week. And he rang me up. It's 5:30 one afternoon and he rings me up. And he says: "[name], I'm just about to interview Peter Dunne [i.e. NZ Minister of Health] at 7 o'clock". You know, an hour and a half to go... "Can you explain to me how the law actually works?" But he had been running all his stories for over a week before he bothered to find out what the law did!* (KI-9, NGO)

### **Regulatory management and workload during the interim regime**

The delays in finalising the full PSA regulatory framework, initially projected to be completed by the end of 2013, attracted criticism from many key informants, who thought that some of the identified problems were exacerbated with time. When invited to explore reasons for the delays, several key informants commented that the timeline for developing regulations was never realistic and that the amount of work was initially underestimated. One key informant compared the task of developing regulations for the full regime and managing the interim PSA market to *'changing the tyre in a car while the car was driving along'* (KI-25, health professional).

Key informants directly involved in the regulatory process stressed that the management of the interim regime took much of their resources, leaving little time and personnel to work on the regulations. They stressed the *'behind the scenes'* work, such as responding to the legal challenges from the industry and numerous media queries about the new regime. Overall, they

perceived they had limited political, public and local community support during the interim regime. A couple admitted faults in the planning stage, including that there was much regulatory work to complete when the interim regime was established:

*The biggest problem was lack of preparation for "day 1" - the implementation. And even though we had all this planning, and risk assessment, that was never the reality... There's always much more. And I think... Personally, in my naivety, apart from inexperience of me as a regulator, I was just fighting fires, the whole time...instead of trying to plan something, I was just reacting, reacting, reacting.* (KI-15, civil servant)

While most key informants in this study praised the regulatory ideas behind the PSA, they expressed dissatisfaction with how the interim regime was managed. *'The original intention of the Act got lost, got lost in translation'* – was one participant's comment (KI-13, law enforcement).

## **Conclusions and Discussion**

The challenges experienced during the interim PSA regime provide a number of learnings for those considering regulatory approaches to recreational psychoactive drugs, including NPS and the emerging legal regimes for cannabis.

Perhaps the most important is that the process of establishing a recreational drug market requires considerable resources, time and planning. Key informants in this study attributed many challenges experienced during the interim PSA regime to truncated timeframes, resource constraints and insufficient planning. For example, the Select Committee process for the PSA was reduced from a standard six-month period to two months (New Zealand Parliament, 2013b). Reports on the implementation of legal regimes for recreational cannabis in Uruguay and US states support this observation. For example, in Washington one year and eight months passed from the legalisation of the sale of recreational marijuana by ballot to the opening of the first recreational stores (Roffman, 2016). In Uruguay, where the bill to regulate cannabis was signed into law in December 2013, it took eight months to develop regulations and launch the registry of home-growers, 10 months to launch the registry of cannabis clubs (Walsh & Ramsey, 2015), and sale from pharmacies is yet to be fully implemented (as of December 2016) (Martínez, 2016).

Many key informants in this study believed that the main challenge which led to the ending of the interim PSA regime in New Zealand was ongoing community opposition to the legal sale of

psychoactive products. To our knowledge there was no baseline data (i.e. pre-PSA) on attitudes towards recreational use of legal highs in New Zealand. The MOH Report analysing submissions to the PSA Bill summarised that ‘around three quarters of the submissions were broadly supportive of the Bill’ (MOH, 2013a). Our retrospective analysis of written submissions to the Psychoactive Substances Bill indicates that the support was higher among submitters representing organisations (95%, i.e. 40 out of 42 submissions from organisations supported the PSA regulatory approach), than among individual submitters, with 50% (n=36) supportive, 32% (n=23) opposing and 18% (n=13) unclear in their opinion about the regulated market approach. There was also some lack of understanding of the intention of the law with 10% (n=7) of individual submitters claiming to support the PSA under the understanding that it intended to impose a blanket ban on all ‘legal highs’. An online poll conducted in October 2013, i.e. three months into the interim PSA regime, showed that 35% of respondents (1524 votes) agreed with New Zealand’s new synthetic drugs law as ‘a pragmatic response’ (Wilkins, 2014b). By the end of the interim regime, 85% of online respondents supported the banning of all interim approved products (Smith, 2014).

These results highlight the importance of engagement with the public and media about the aims of the new policy and clear policy communication throughout the process of implementation. The public ballot process employed in Washington, Colorado and Alaska to determine if cannabis should be legalised provided a ready-made process to engage with the public. In Uruguay, in contrast, where marijuana was legalised by national legislation, public opposition to the law has been identified as a significant challenge to the implementation process (Walsh & Ramsey, 2015).

With regard to regulating retail sales of new psychoactive products, numerous studies have found that greater outlet density is associated with increased alcohol and tobacco harms (C. Campbell et al., 2009; Novak, Reardon, Raudenbush, & Buka, 2006). However, participants in this study identified that limitations on outlet density during the interim regime resulted in an unintended consequence of attracting large numbers of customers to a reduced number of retail outlets, which they thought increased social disruption and in turn became the focus of negative media attention. There was approximately one licensed retail outlet per 29,000 people under the interim PSA, which makes outlet density similar to that of coffee shops in the Netherlands (1 shop per 27,000 people, with 614 coffee shops registered in 2014 (Niesink, Rigter, Koeter, & Brunt, 2015)). It is lower than the density of retailers and medical dispensaries under the newly established regime in Colorado (approximately 1 shop per 6,500 residents) and the density

intended for the regulated cannabis market in Washington State (expected to be one shop per 20,000 residents) (Caulkins & Kilmer, 2016).

The implementation of a workable retail environment during the interim regime was further hampered by the opposition to the new regime from some local councils, who in some cases effectively banned any stores from their regions. The extent of power given to local communities in implementing laws regulating availability of recreational drugs is an important part of the legal regulatory regime, and requires clear and explicit provisions. In New Zealand, many local councils took a pragmatic approach to LAPPs. For example, Auckland Council (local government body for New Zealand's largest city), established restrictions on the location of licensed retailers based on the socioeconomic deprivation index of the neighbourhood (as measured by Census data), with complete bans on stores in high deprivation areas (Auckland Council, 2015). Commentators on the new cannabis regimes have argued that a patchwork of local regulations creates uncertainty in the market (Ghosh et al., 2015; Roffman, 2016). For example, in Washington, following a period of uncertainty, the Attorney General interpreted that local governments *have* the right to ban cannabis-related businesses from their jurisdictions (Roffman, 2016) and 78 cities and four counties have done so (as of August 2016) (Municipal Research and Services Center, 2016). In Uruguay, the opposition to cannabis legalisation from pharmacists questioned the feasibility of this distribution channel for government-licensed cannabis (Wang, 2014). Again, engagement with relevant stakeholders early in the process may secure more local support for retail outlets.

Experience with regulating legal markets for alcohol and tobacco provide some insights on how to mitigate harms from new psychoactive products (Hall & Lynskey, 2016b; Pacula et al., 2014). Price control is often cited as one of the most important regulatory tools to restrict alcohol and tobacco use, particularly by young people and heavy users. In the US states where cannabis has been legalised or legalisation is being considered, there has been extensive policy debate about how to regulate the price of cannabis, e.g. what tax rate to apply and what the tax base for these products should be (i.e. weight of a drug sold, value of a drug or a 'unit of intoxication') (Caulkins & Kilmer, 2016). In Uruguay, where tax revenue was not central to cannabis law reform, a 'variable fee' will be used to keep the price 'competitive with the black market' (Walsh & Ramsey, 2015). In New Zealand, however, no specialised price control mechanism applied to interim approved products apart from a standard universal value-added sales tax, and this was highlighted as a gap by several key informants in this study and public submitters on the original PSA Bill. The lack of price control provisions under the PSA means there was no additional

mechanism to control interim product prices and heavy price discounting of products was reported as competition increased (Rychert & Wilkins, 2016a).

As identified by our study participants, policy design and implementation also failed to address education and prevention. Consumers of products approved to be sold on the interim market were not actively targeted with messages about how to safely use products and likely health effects, except for the compulsory health warnings on the packaging, or advice volunteered by retail staff. Public information campaigns are required, especially focusing on vulnerable populations such as youth and Maori.

Since the ending of the interim regime, work on PSA regulations has continued and the regime is now ready to receive product applications under the full PSA testing framework. However, no applications for approval have been made to date (as of December 2016). With no products currently approved for sale on the legal market, the PSA essentially results in a “blanket ban” on NPS supply, much like the recent UK Psychoactive Substances Act 2016 (Rychert & Wilkins, 2016b; Wilkins & Rychert, 2017). The ban on the use of animals for the testing of products, imposed by the amendment to the PSA in May 2014, was identified as a major challenge to moving the regulatory regime forward, as product sponsors are unable to provide sufficient safety data to achieve a product approval (Rychert & Wilkins, 2015b; Schep et al., 2014). Strategic analysis of the situation suggests there do appear to be several viable options to obtain the necessary data for regulatory approval without the use of animals, but they would require political support (Rychert & Wilkins, 2015a). The findings from this paper suggest that a wider discussion about the potential benefits of regulation may be needed to create the necessary public support and engagement with local governments and communities to ensure future success.

We acknowledge a number of limitations with our study. First, our study explored challenges with the implementation of the PSA drawing on experiences of information-rich key informants from various backgrounds. Their observations were based on their own perceptions of the situation which were of course coloured by their self-interest. We interviewed a range of key informants from different sectors in an effort to provide a balanced appreciation of the issues. Most participants were supportive of the regulatory approach in the PSA and hence were open to providing constructive criticism of the implementation. The interviews were conducted 17 to 21 months after the ending of the interim regime which may have further facilitated frank and open discussion of issues.



## **Chapter 7: Legal high industry business and lobbying strategies under a legal market for new psychoactive substances (NPS, ‘legal highs’) in New Zealand**

A number of challenges with controlling the legal high industry during the interim regime were identified in the previous two chapters. For example, in Chapter 5 I discussed how the litigious approach of the industry challenged the speed and efficiency of regulatory decision-making in regards to products and in Chapter 6 I described the strategies the industry developed to “creatively comply” with new PSA regulations on retail. This chapter goes on to explore the business and lobbying strategies of the legal high industry in depth.

In contrast to Chapters 5 and 6, where views of key informants from various backgrounds were explored, this chapter focuses on the observations of industry-related actors only. I explore how the industry viewed changes in the regulatory environment, competition in the market and how they responded to emerging challenges, including their attempts to self-regulate. Better understanding of industry motivations and business strategies can help inform effective implementation and enforcement of the regime in the future.

The paper comprising this chapter is published in the *International Journal of Drug Policy*. Findings were presented during the *International Society for the Study of Drug Policy* satellite conference event in Auckland, New Zealand (11-12 May 2016). I also provided additional commentary on this study and its implications for the new regulated market cannabis regimes in the US context for *Alcoholism & Drug Abuse Weekly*, an American magazine for policy and programme decision-makers (see: Enos, 2016).

Rychert, M. & Wilkins, C. (2016). Legal high industry business and lobbying strategies under a legal market for new psychoactive substances (NPS, 'legal highs') in New Zealand. *International Journal of Drug Policy*, 37, 90-97. Doi: <http://dx.doi.org/10.1016/j.drugpo.2016.08.011>

## **Abstract**

**Background:** The establishment of a regulated legal market for new psychoactive substances (NPS, 'legal highs') under New Zealand's *Psychoactive Substances Act (PSA)* 2013 created a new commercial sector for psychoactive products, previously limited to alcohol and tobacco.

**Aim:** To explore how the newly-recognised 'legal high' industry (LHI) viewed and responded to the changing regulatory and market environment.

**Methods:** In-depth interviews with six key informants (KI) from the LHI: a leading entrepreneur, chemist, industry spokesperson, retailer, product buyer and a researcher commissioned by the LHI – were conducted, transcribed and analysed thematically. Formative work for the study included review of official LHI documents (websites, public submissions, self-regulation documents).

**Results:** The LHI stakeholders espoused an idealistic mission of shifting recreational users of alcohol, tobacco and illegal drugs towards "safer alternatives". Passage of the PSA was viewed as a success after years of lobbying led by pioneering LHI actors. The growth and professionalisation of the LHI resulted in an increasingly commercial market which challenged idealistic views of the original operators. LHI KI reported the targeting of young and low income customers, price cutting and increasing the strength of products as business strategies. Attempts by the LHI to self-regulate did not prevent escalation in the strength of products and fall in retail prices. The LHI reported outsourcing of manufacturing and exporting of their products to other countries, demonstrating an international business model.

**Conclusions:** There was a tension between profit and idealistic motivations within the LHI and this increased as the sector became more commercialised. While the LHI distanced itself from both alcohol and tobacco, they reported the use of similar marketing, business and political lobbying strategies. Rules for engagement with new 'addictive consumption industries' are required to clarify the role they are permitted to play in the development of regulatory regimes for new psychoactive substances.

## Introduction

Until recently, legal markets for recreational psychoactive products were limited to alcohol and tobacco products. Recent drug law reforms in a number of countries have created new sectors for recreational psychoactive products, including a regulated market for cannabis in a number of US states (Roffman, 2016; Room, 2014) and in Uruguay (Walsh & Ramsey, 2015) and a regulated market for new psychoactive substances (NPS) ('legal highs') in New Zealand (Wilkins et al., 2013).

There is an extensive literature examining the tensions between the commercial interests of the alcohol and tobacco industries and public health goals (Adams, 2013; Adams, Buetow, & Rossen, 2010; Babor, Caetano, et al., 2010; Casswell, 2013; Moodie et al., 2013; West & Marteau, 2013). A number of academics have attempted to translate the lessons learnt from regulating the alcohol and tobacco sectors to the new recreational psychoactive industries, particularly in the case of legal recreational cannabis (Caulkins, 2016; Caulkins, Kilmer, & Kleiman, 2016; Pacula et al., 2014; Room, 2014). This emerging literature has focused on how to regulate the new commercial drug markets from the legislative and regulatory perspective, including how to design regulations to mitigate public health harms (Ghosh et al., 2015). Little research has been completed on how the new 'addictive consumption industries' view and respond to this changing market and regulatory environment.

New Zealand has been at the forefront of the legal high phenomena with a large scale legal high industry (LHI) operating since the early 2000s (Sheridan & Butler, 2007; Wilkins & Sweetsur, 2010). However, it was only in 2013, following the passage of the *Psychoactive Substances Act* (PSA) 2013, that the industry received full official legal recognition and became subject to licensing, auditing and reporting requirements (New Zealand Parliament, 2013a). This paper explores how the LHI actors in New Zealand viewed and responded to the changing market environment in which they were operating, with a particular focus on their attempts to self-regulate, lobby the political system and develop profitable business strategies. Understanding industry motivations and business strategies can help inform effective implementation and enforcement of new regulatory regimes.

## Historical background: the evolution of LHI in New Zealand

In the early 2000s New Zealand experienced an emerging market for so called 'party pills' containing mixtures of benzylpiperazine (BZP) and trifluoromethylphenylpiperazine (TFMPP)

(Wilkins & Sweetsur, 2010). Initially unregulated (i.e. with no legal limits on age of purchase, promotion or place of sale), BZP/TFMPP 'party pills' varied in strength and quality, and were sold from counter culture stores and increasingly from local convenience stores (Sheridan & Butler, 2007). By 2004, approximately five million legal BZP/TFMPP party pills had been sold, amounting to sales of 24 million New Zealand Dollars (NZD) per year (15 million EUR = 17 million USD) (Wilkins & Sweetsur, 2010). The first major LHI company and lobby group *Stargate International* was established around this time (STAR stands for *Social Tonics Advocacy and Research*), followed soon after by the closely-linked party pills industry association STANZ (*Social Tonics Association of New Zealand*). STANZ developed a voluntary 'Code of Practice', a nine-page document covering aspects such as the quality and dosage of BZP products (including maximum strength), labelling and packaging (including the warning 'do not consume with alcohol') and retail sales. The STANZ Code endorsed the sale of BZP party pills from licensed alcohol retailers under the assumption that retail staff would be trained to check age identification and in refusing sales to intoxicated customers (STANZ, 2007b).

In 2005, the manufacture and sale of BZP pills was formally recognised as a legal commercial activity under the new Restricted Substances Regime (RSR) and became subject to broad regulatory restrictions such as age restrictions on purchase (R18), restrictions on advertising in major media and bans on the giving away of free samples as part of promotional activities (Sheridan & Butler, 2010). More detailed government regulations for the RSR were intended, including product quality standards and maximum dose limits, but they were not introduced until late 2008 by which time BZP had already been prohibited. The LHI responded to the lack of progress with regulation by commissioning a public law firm to draft regulations for BZP (STANZ, 2007c) and a Code of Good Manufacturing Practice (STANZ, 2007a), which were subsequently submitted to the government (STANZ, 2007d). In 2007/2008, at the height of BZP party pills popularity, the industry was selling as many as 200,000 party pills per month, with a product range of around 80 to 120 different brands and estimated turnover of 25-35 million NZD per year (18-25 million USD = 16-22 million EUR) (Wilkins et al., 2013). The lucrative market for BZP/TFMPP party pills was brought to an end in 2008 when BZP was scheduled as a class C drug under the Misuse of Drugs Act (MODA), following new evidence of BZP-related health harms. After the ban on BZP, STANZ ceased its self-regulatory activities, but the industry lobby group (*Star Trust*, which took over advocacy activities from Stargate) continued.

The LHI responded to the ban on BZP by shifting production to non-BZP party pills and synthetic cannabinoids, which at this time were not controlled by any legislation (Wilkins et al., 2013).

Between 2011 and 2013 a number of products were taken off the market by means of Temporary Class Drug Notices (TCDN), which allowed the New Zealand Minister of Health (MOH) to ban specific substances for up to two years pending their risk-evaluation. TCDNs were eventually imposed on 33 compounds including JWH-018 and JWH-073, ingredients in the Spice and Kronik brands of synthetic cannabinoids (MOH, 2011b). Despite the bans on some compounds, the MOH estimated in 2013 that approximately 200–300 psychoactive products were being sold from around 3,000–4,000 retail outlets, mostly local convenience stores, and that the market was larger than the former BZP market at the height of its popularity (MOH, 2014f). The MOH suggested that this “may demonstrate a shift towards more aggressive marketing practices by industry” (MOH, 2012).

In July 2013, the New Zealand government passed the *Psychoactive Substances Act* (PSA), which established a regulatory framework for the manufacture and sale of “low risk” psychoactive products. Under the PSA, product sponsors are allowed to legally sell their products from licensed specialised retail outlets if they provide evidence from toxicology and clinical trials that their products are “low risk” (Wilkins, 2014a). Six risk criteria to evaluate products for regulatory approval are specified in the legislation, i.e. toxicological effects, risk to public health, potential to cause death, potential to create dependence, likelihood of misuse and appeal to vulnerable populations (New Zealand Parliament, 2013a). This regulated market approach was recommended by the New Zealand Law Commission (NZLC) as part of their review of the *Misuse of Drugs Act* (MODA) (NZLC, 2011). As part of the process of writing their report, the NZLC had engaged in ‘targeted consultation’ with various stakeholders, including with LHI actors. The LHI also went on to provide public submissions to the final Law Commission Report (2011), the Psychoactive Substances Bill (2013) and further regulatory instruments related to the PSA such as the Psychoactive Substances Regulations (2014).

Much of the regulation required to make the new regulatory regime fully operational had not been developed at the time the PSA was enacted, including the specific toxicology and clinical studies required to prove products are “low risk”. Consequently an interim regime was established while regulations were developed (Wilkins, 2014b). This allowed the LHI to continue selling products under new PSA retail, advertising and quality standard restrictions. Forty-seven products were granted interim product approvals, with 40 being synthetic cannabinoid smoking blends. One hundred and fifty-three specialised retailers were licensed to sell products (down from an estimated 3,000–4,000 retailers, mostly local convenience stores, before the interim regime) and 10 companies were licenced to manufacture (Wilkins, 2014b). Following passage of

the PSA, the LHI established the *Psychoactive Industry Training Association* (PITA) with the aim of ensuring that retailers associated with PITA complied with the new PSA retail regulations (Star Trust, 2013). PITA released a retailer 'Code of conduct', a one-page document containing 10 bullet points which endorsed practices such as "fair business", "truthful marketing", "cultural sensitivity" and "environmental responsibility" and promised random audits of associated retailers to "help maintain [PSA] standards" (PITA, 2013a, 2013b). An estimated 3.5 million packets of product were sold during the 10 months of the interim PSA regulated market, with an estimated 140 million NZD (88 million EUR = 99 million USD) in annual retail sales (MOH, 2014f).

In May 2014, the interim regime was brought to an abrupt end by a Parliamentary amendment to the PSA due to on-going reports of social disruption around retail stores and adverse effects from interim products such as vomiting, agitation, and anxiety (Glue et al., 2016; Wilkins, Prasad, Wong, et al., 2016). However, work on regulations continued and in November 2014 the Psychoactive Substances Regulatory Authority (PSRA) announced the regime was open to receive and assess product applications under the newly released Psychoactive Substances Regulations 2014 and related "Product Approval Testing Guidelines" (MOH, 2014d; PSRA, 2014a). No product applications have been received to date (as of August 2016) with the ban on the use of animals for the testing of products identified as a major challenge to obtaining the necessary evidence for regulatory approval (Rychert & Wilkins, 2015a, 2015b; Schep et al., 2014). However, as of August 2016, five entities hold full PSA licenses to conduct research on psychoactive substances, including one company linked to a pioneering LHI entrepreneur.

## Methods

A range of industry reports and documents were reviewed as formative work for the study, including industry association websites ([www.legalhighs.co.nz](http://www.legalhighs.co.nz), [www.stargateinternational.org](http://www.stargateinternational.org), [www.thestartrust.org](http://www.thestartrust.org)), public submissions to the PSA from the industry associations and LHI manufacturing and retail businesses ("Submissions to the Psychoactive Substances Bill 2013,"), self-regulation resources (i.e. STANZ and PITA codes of conducts and manufacturing practice), an industry funded research publication (Noller, 2014) and an industry conference presentation ("What happened under a regulated market?", Star Trust). Formative work also included a review of official public policy documents related to the enactment of the PSA, i.e. all 114 public submissions to the PSA, six sets of parliamentary readings on the Psychoactive Substances Bill and the Psychoactive Substances Amendment Bill (New Zealand Parliament, 2013b, 2014b), and four MOH Regulatory Impact Statements (MOH, 2011a, 2012, 2014f,

2014g). These secondary documents informed the interview guide and selection of LHI stakeholders to be interviewed.

While a large number of retail outlets were involved in selling legal highs in New Zealand at one time or another, the importation, manufacture and wholesale side of the sector comprised only a handful of operators. For example, as noted, only 10 interim licenses to manufacture products were ever issued under the interim PSA regime. To investigate the motivations and business strategies of LHI, key members of the industry were invited to participate in the study. In-depth face-to-face interviews were conducted with information-rich LHI key informants (KI), including a leading entrepreneur, chemist, industry spokesperson, retailer and a product buyer, and one interview with an independent researcher commissioned by the LHI. A total of nine industry actors were contacted, of which six were interviewed for the study. Two of those contacted did not respond to the invitation and one more was unable to schedule an interview time within the timeframe of the study. Some of the key informants interviewed had over ten years' experience in the legal high sector in New Zealand having operated during the BZP market in the early to mid-2000s.

A semi-structured interview guide was used to explore participants' experiences with the changing market and regulatory environment. Interviews were conducted from December 2015 to January 2016. Five interviews were conducted in person and one by Skype video conference. Interview times ranged from 70 to 114 minutes, with a mean duration of 87 minutes. All interviews were conducted, recorded and transcribed by the first author. Deductive and inductive coding was completed by the first author to identify themes in the data (Patton, 2015). The second author coded one interview transcript, after which themes were compared and finalised through discussion between the two authors. A qualitative description approach, characterised by low-inference interpretation (Sandelowski, 2000), was used to analyse data and report findings. The project was evaluated as low risk and registered with the Massey University Human Subjects Ethics Committee.

Due to the small number of LHI actors interviewed and the sensitive nature of the topics discussed we do not attribute quotes to specific LHI individuals.

## Results

### LHI motivations

LHI key informants emphasised drug law reform as a motivation for their involvement in the legal high market. A couple of participants stressed their *“involvement in cannabis law reform”* (KI-1) and that they personally aimed to achieve *“some movement on the cannabis law”* (KI-3). Some focused on health-centred aims, i.e. to provide users of recreational drugs, including alcohol, tobacco and illegal drugs, access to lower risk, safer alternatives. They commented that the LHI aimed to change consumers’ habits with the aim of reducing overall drug related harm:

*“[In mid-2000] We shifted people from smoking meth and snorting meth to taking [BZP] party pills, and they were quite happy to do that. But can we shift people who want to get stoned from having to smoke every couple of hours to having one pill at the start of the night, and enjoy that warm sociable experience over a few hours and then it will fade away, and not having to smoke anything at all?”* (KI-4)

### Keeping a distance from “Big Tobacco” and “Big Alcohol”

LHI key informants appeared to distance themselves from the tobacco and alcohol sector and referred to these products as the *“most harmful”* (KI-4) or *“really dangerous drugs”* (KI-2). They felt their sector was unduly penalised in comparison to the alcohol sector. Restrictions on the number of licensed legal high retail outlets were given as an example of *“unfair”* treatment (i.e. 153 legal high retailers were licensed to operate during the interim PSA regime compared to 14,517 licensed alcohol outlets operating as of September 2013 (Ministry of Justice, 2013)). A couple of LHI key informants went so far as to claim that the vested interests of “Big Alcohol” played some role in the amendment to the PSA in May 2014 which ended the interim PSA regime. These key informants perceived that the alcohol industry saw the LHI as market competition:

*“We wanted to focus on the most harmful drugs and find safer alternatives to them, and obviously the most harmful was alcohol, and it's not that hard to find another GABAergic psychoactive, which is broadly similar or even preferable in effects to alcohol, with a far lower toxicity profile. That wouldn't be a difficult project to embark on. So when we started talking about this in the media, the alcohol industry realised that under this regime their products would eventually be phased out.”* (KI-4)

## **Political advocacy of LHI**

LHI key informants viewed the establishment of LHI lobby groups and their political activity as a positive development, which increased legitimacy of the industry and ultimately led to the passage of the PSA. LHI key informants mentioned various ways of engaging in discussions with politicians and government officials, such as official public submissions and informal consultations. Presenting the international perspective was seen as an important element of lobbying for change toward a regulated market approach:

*“They [New Zealand government] were concerned with the international perspective, we [the LHI industry] invited international experts to become involved in the consultation on the Bill, which I think was well received.” (KI-4)*

The political lobbying was financed and led by pioneering LHI players who entered the market in the early 2000s. LHI actors involved in the political advocacy viewed the approach they took as professional; they saw this professionalism as evidenced, for example, by outsourcing drafting of official industry input to policy to a public law consultancy firm:

*“Our budget for the policy development has gone into millions of New Zealand dollars over all these years. (...) We chose the best people in policy development that we could. And yes, a lot that we made went into policy development, not buying Ferrari or Lamborghini.” (KI-4)*

One LHI key informant commented on the goals of actors involved in the policy development. S/he commented that science should play a greater role in the process of developing regulations for the commercial drug market:

*“I thought there should be more scientists involved. I guess there should have been more people without financial interest in that industry involved in creating the regulations. But also people who weren't invested morally one way or the other as well... you know, neutral people.” (KI-6)*

## **The challenge of industry growth**

The growing size of the legal high sector in New Zealand until the PSA was passed was attributed to the largely unregulated nature of the synthetic cannabinoid market until mid-2013. As one LHI key informant described, *“the industry was sort of quite easy to enter”* (KI-1). Growth of the industry was seen as a negative development by several LHI key informants, who thought that

some new businesses were not interested in responsible marketing and joined the industry purely for financial reasons:

*“At the beginning it was limited to a small number of [legal highs] suppliers who had quite good motives, like we did. (...)Then, it was all of these kind of copycats, who joined them and thought “I can make a lot of money”. And every time there's a big expose in the news you would then see a few months later, oh, here's a whole lot of bunch of new people coming to the market, cause they thought they showed it on the telly, and they all gone to Google and decided that they could do it too.” (KI-1)*

### **Benefits and pitfalls of industry professionalization**

Professionalisation of the LHI followed market growth, manifesting itself in division of responsibilities within LHI businesses and specialisation of personnel with skills in distinct areas, such as chemistry or marketing. LHI key informants outlined some benefits of the professionalisation process such as improvements in manufacturing practices, e.g. the shift from the homemade “spray and dry” method of synthetic cannabis production to the use of commercial food manufacturing equipment, which resulted in improved consistency of products. On the other hand, a couple of LHI key informants thought that the new personnel “*didn't know much about drug use*” (KI-3) and focused on goals specific to their professional background. This was sometimes viewed in negative terms:

*“[The general manager's] background was... he was an award-winning sales manager from [major retail company]. You know, he was great at promotion, he was great at the ‘hard sell’ and getting people to buy things that they don't really need and all that kind of thing. And after he became the manager things really turned downhill, because the safety of the products and the wellbeing of consumers and stuff really just went out the window. And all he cared about was just sales and profit. And, I mean, he was good at his job. I'm not going to say he didn't do well, he made a huge amount of profit” (KI-3)*

### **Marketing towards youth and low-income customers**

All LHI key informants distanced themselves from targeting young or low income customers. One LHI key informant went as far as to claim that “*the average consumer [of interim approved legal synthetic cannabis product] is someone in a job, probably married, with kids, probably over 30*” (KI-2). While expressing personal disapproval of targeting young and low-income customers,

they reported that some businesses engaged in this type of product marketing. One LHI key informant described how this was done in his/her company:

*“And of course the people that consume the most of these drugs are not educated professionals in their late 20s, they are uneducated people in their teens. (...) Those are the people who were buying 80 to 90% of the products. (...) You know, all of these vast amount of sales and windfall profits, they were all from customers that were around 19 years old. That was never an ethically appropriate thing to be doing in the first place. I didn't think it was appropriate to be selling to those people. But at the end of the day, I wasn't in charge of sales, and, you know, 19 year olds buy a lot more stuff than 29 year olds do.” (KI-3)*

### **The decline in product prices**

All LHI key informants commented on a continuous drop in the price of legal high products. One participant recalled that the early synthetic cannabinoid product Spice was first sold in 2008 in his/her outlet for 120 NZD (76 EUR = 85 USD) per 3 grams and then *“it slowly came down”* (KI-1). Several LHI key informants reported that the average price of the interim PSA approved products in 2013 fell to around 20 NZD (13 EUR = 14 USD) per package (2.5 grams), with some retailers selling *“for less than 20 dollars”* (KI-6). Following the establishment of the interim PSA regime, when the formulation and strength of interim approved products could no longer be modified, the price was the main means of gaining a competitive market advantage. This was thought to contribute to the ongoing decline in prices:

*“[Following passage of the PSA] the prices went down and there were price wars and that was terrible.” (KI6)*

### **Price control as a means to ensure a more responsible client base**

The decline in retail prices meant that retailers with higher prices were at a market disadvantage compared to retailers who discounted their products. On the other hand, maintaining higher prices allowed market operators to maintain a good reputation as a *“responsible retailer”*, something particularly important for larger retail chains. A couple of key informants reported imposing higher prices as a means to ensure a more responsible client base:

*“Having high prices went against us financially, but for us in terms of keeping our store away from other people. Because it meant that we didn't have children, or underage*

*people, who were asking an adult to buy for them... But then a lot of other retailers who had very low prices, they would make a lot of sales, but they would deal with pretty dark people.” (KI-6)*

### **Brand reputation for product safety**

LHI key informants made comments about the tensions between financial profits and brand reputation for safety. They identified that customers tended to desire higher strength products and hence there was pressure to supply these products:

*“We did develop several products which were at least significantly lower risk, such as [product name], but this was perceived as not strong enough by users, and since it failed to sell, retailers didn't order more and we stopped making it.” (KI-3)*

However, the LHI key informants also recognised that products had to be safe in terms of potency and of consistent quality to retain existing customers:

*“Because, you know, you really don't want people ending up in hospital because of your product. Not just because of, uhmmm, you know, getting it pulled... but even word of mouth among customers. You know, an adverse reaction like that was bad for the brand.” (KI-6)*

### **LHI self-regulation and its effectiveness**

All the LHI key informants interviewed were affiliated with companies who joined voluntary agreements to self-regulate under STANZ (during the BZP period) and PITA (following passage of the PSA). They commented that the early self-regulation instruments were the industry's response to the lack of government regulations and growing market competition which manifested itself in escalating strength of BZP party pills. LHI key informants mentioned two motivations for the industry in engaging in collective action, i.e. increasing industry legitimacy and increasing brand reputation. A couple of LHI key informants claimed that the latter was sometimes abused by “irresponsible” members of the industry:

*“All the kind of good side of industry joined. But also a bunch of people who weren't so good, but wanted to join to make them look good. And the guy from [company name] would be an example of that. They kind of cuckooed into PITA after there've been controversy about what they were getting up to, and then they joined PITA and started*

*to go to all the meetings and playing in front of the council "Oh, we're really responsible", and all of that. (KI-1)*

While seen as necessary and worthwhile overall, a couple of interviewees questioned the scope and effectiveness of industry self-regulation. One LHI key informant commented that membership of STANZ and PITA was limited to manufacturers and retailers operating in the biggest cities, and mostly in the North Island of New Zealand. Another key informant, the researcher commissioned by the LHI, commented on the limited scope of measures to self-regulate the synthetic cannabinoid market under PITA:

*"They were trying... they had this organisation called PITA... They gave me some forms when I was writing the report, and they had things like recycling paper, and I said "mate, this is crap, you've got to get serious about this. If you really want to do some decent stuff for your industry... you know, talk about building relationships with drug treatment services, talk about training people to recognise problem customers, people who got problems". (KI-5)*

### **The impact of the global legal high market**

Several LHI key informants made comments about being part of a global market for legal highs. They reported that the process of product development included designing chemical compounds domestically, importing active ingredient from China, manufacturing the final product domestically, and finally wholesale distribution of the final product in New Zealand as well as on export markets. Given the international business model of the LHI, legislative and regulatory changes in other countries were reported to have influenced product development decisions for the New Zealand market:

*We weren't only selling compounds in New Zealand, we were selling compounds in Australia, we were selling them in the UK, Canada, South Africa, Russia, all around the world. So the drug law changes in all these countries were also quite influential for what we used here, because, you know, if a compound got banned in the UK, and they got banned earlier than they did here, then we just switched our Chinese manufacturer to make something that wasn't banned there, so then that meant that they had a large amount of that available in China so we could just get them to send it here as well [into New Zealand]. (KI-3)*

One industry actor suggested that the regulatory and legislative landscape in other countries also influences current product development decisions, and that the choice of a psychoactive

substance to be marketed as a “low risk” product for approval under the full PSA regime may be affected by the drug and consumer laws in other jurisdictions.

## **Discussion and conclusions**

Interviews with LHI actors highlighted tensions between the idealistic health promotion motivations as espoused by pioneering operators and the commercial demands of the regulated market, and this tension increased as the market became more competitive. It is by no means clear that the LHI industry was achieving its goal of providing “safer drug alternatives”. A number of New Zealand studies identified serious health problems and issues of dependency related to the use of approved synthetic cannabinoids products sold during the interim regime (Glue et al., 2016; Glue et al., 2015; Macfarlane & Christie, 2015; Wilkins, Prasad, Wong, et al., 2016). The small number of studies comparing the physical and mental health risks between synthetic cannabinoids and natural cannabis suggest that synthetic cannabinoids are more harmful (Nia, Medrano, Perkel, Galynker, & Hurd, 2016; Winstock, Lynskey, Borschmann, & Waldron, 2015) and that users prefer natural cannabis over synthetic cannabinoids (Winstock & Barratt, 2013).

Despite distancing themselves from the alcohol and tobacco sectors, the industry actors reported that some LHI businesses used similar business strategies, such as marketing their products to youth and low income customers (for literature on the use of these strategies by alcohol and tobacco see for example: S. Anderson, Hastings, and MacFadyen (2002); Jackson, Hastings, Wheeler, Eadie, and Mackintosh (2000); Seidenberg, Caughey, Rees, and Connolly (2010)). Participants in our study identified decreasing prices and increasing the strength of products as important ways of achieving sales success in the legal high market. Although US cannabis regimes are still developing, the initial reports from Colorado and Washington, where some of the world’s first seed-to-sale legal recreational cannabis markets have been established, show that the new legal cannabis industry has employed similar strategies, including marketing high potency cannabis products (Subritzky, Pettigrew, & Lenton, 2016). Concentrates as potent as 95% THC have been sold on the legal recreational cannabis market in Colorado, and the average potency for cannabis flowers stands at 17.1% THC (Orens, Light, Rowberry, Matsen, & Lewandowski, 2015). The price of legal cannabis products is also reported to have declined in Colorado and Washington (Caulkins et al., 2016; Jensen & Roussel, in press). For example, the retail price of recreational cannabis in Washington fell from around 20 USD per gram when the first shops opened in July 2014 to 9.32 USD per gram in March 2016 (Humphreys, 2016). Some analysts of the legal cannabis industry have suggested that with further economies of scale and production efficiencies wholesale prices for cannabis could eventually fall to as little as \$10-20

USD per pound of cannabis flowers (Caulkins et al., 2016). However, some LHI actors in our study recognised the value of higher prices and potency controls as a means to ensure a sustainable and reputable business sector, suggesting there is possibly space for cooperation with the government regarding these aspects of market regulation.

While government regulation is central to effectively managing the tension between the profit motivations of new addictive industries and public health goals, the industry also has a stake in ensuring that all operators follow certain standards of good practice. The LHI in New Zealand was successful in combining their lobby efforts to secure legal recognition of their industry, but failed to prevent market escalation toward stronger products and lower prices. This again demonstrates that there are good reasons to be sceptical about the effectiveness of self-regulation by addictive consumption sectors, reflecting experiences from the tobacco and alcohol sectors (Hastings et al., 2010; Pollay, 1994). However, if new industries perceive that their survival may depend upon effective self-control, they may have more incentive to effectively self-regulate, which could offer some public health benefits when employed *in addition* to government regulation. To this end, industry associations could demonstrate their good faith by “outing” irresponsible operators and unsafe products to provide consumers with clear information about which companies and products fit within their safe guidelines and practices.

In terms of the policy process of developing a legal regulated market for psychoactive products in New Zealand, the LHI were actively lobbying for policy change to a regulated market approach. There is little official information about the extent of the LHI industry involvement in the political processes leading up to a regulated approach to legal highs in New Zealand. The regulatory impact statement to the PSA outlines that “key industry actors” were consulted and “targeted consultations” were held with the LHI in May 2012, but no details were provided about the scope of these consultations and eventual impact on the PSA legislation. In the US, cannabis industry actors can influence political processes by financially supporting members and candidates to Congress through so-called Political Action Committees (PACs) (corporations are prohibited from making direct financial contributions to politicians). The establishment of a PAC by the National Cannabis Industry Association (NCIA) illustrates how industry actors are able to promote industry-favourable policies by working within the political system. On a regulatory level, cannabis industry representatives were included in the multidisciplinary “task force” charged with developing early recommendations on how to regulate the recreational marijuana market in Colorado (Amendment 64 Task Force, 2013; Kamin, 2015), and continue to be included

in “work groups” fine tuning details of regulations. This has sometimes resulted in what has been described as “regulatory paralysis due to lack of consensus” (Subritzky, Pettigrew, et al., 2016). Most recently, lawmakers voted down a proposal to limit the potency of legal cannabis in Colorado to 15%, with the industry representatives arguing that the proposal was “unconstitutional” and would drive users to the black market (Ingold, 2016). The cannabis industry in the United States has also been reported to have “pressured regulators to weaken pesticides regulations” (Subritzky, Lenton, & Pettigrew, 2016). This illustrates why many view any relationships between policymakers and the ‘addictive consumption industries’ as unacceptable, and call for excluding the new industries from policy debates and regulatory processes altogether.

Article 5.3 of the Framework Convention on Tobacco Control (FCTC) mandates national governments to protect public health policies from the commercial interests of the industry, essentially excluding the tobacco industry from any policy-making processes (WHO, 2008). Given similarities between tobacco and alcohol, calls for a similar approach have been made with respect to the alcohol policy process (Casswell, 2013; Hawkins, Holden, Eckhardt, & Lee, 2016; World Medical Association, 2015). Whether there is sufficient rationale to treat new ‘addictive consumption industries’ differently from the tobacco and alcohol industries needs to be investigated. Perhaps there is potential value in engaging with new addictive consumption industries *on a regulatory level*, and provided they are kept at ‘arm’s length’. For example, given the novelty of the regulatory area and products involved, there might be benefits in ensuring that commercial operators are consulted when details of legislation are drafted so that potential unintended consequences may be fully addressed. The rules for engagement with new ‘addictive consumption industries’ need to be clearly articulated in the future, including the stages and types of acceptable partnerships. Public transparency should also be ensured in communication between government officials and the industry. This also applies to research partnerships and engagement with civil society organisations, as academics and NGO representatives may become increasingly involved in endorsing the interests of the new commercial actors. One participant in this study was paid to write a report for the industry on synthetic cannabinoids and, while there is no reason to believe the resulting publication was not independent, there is clearly a potential for conflict of interest in these types of arrangements.

Finally, the interviews with LHI key informants revealed the international nature of the legal high business, similarly to the alcohol, tobacco and pharmaceutical sectors. This international

business model focus highlights the need for international agreements to supplement domestic regulation of the sector.

We acknowledge a number of limitations with our study. The sample was limited to six individuals and it is possible that other LHI actors may have different views and experiences. However, the key informants interviewed included leading LHI figures in New Zealand, many of whom have been involved in the LHI market for a decade or so, dating back to the BZP party pills market in the mid-2000s. The timing of the interviewing (i.e. 19-20 months after ending of the interim PSA regulated market) and the fact that a couple of participants were no longer working in the legal high industry at the time of interviews also encouraged frank and open answers.



## **Chapter 8: Are government-approved products containing new psychoactive substances (NPS) perceived to be safer and more socially acceptable than alcohol, tobacco and illegal drugs? Findings from a survey of police arrestees in New Zealand.**

Chapters 5, 6 and 7 explored challenges experienced during the interim PSA regime by analysing qualitative data from interviews with key stakeholders involved in the development and/or implementation of the regime. One of the major issues identified by key informants was that of the safety of interim approved products.

This chapter investigates social perceptions about the interim approved products. I explore perceived health risk and social acceptability of interim approved products, relative to other drugs including alcohol, tobacco and traditional illegal drugs. The quantitative data analysed for this exploration of social perceptions came from the New Zealand Arrestee Drug Use Monitoring Study (NZ-ADUM), which provides a yearly snapshot of drug use among 800 police arrestees in New Zealand. For the purpose of preliminary analysis for this chapter, univariate analysis of NZ-ADUM data was completed. Results of the preliminary univariate analysis are included in Appendix J. The initial statistical analysis gave me insight into the data and informed the subsequent multivariate model as presented in this chapter.

The paper comprising this chapter has been accepted for publication by the *Drug and Alcohol Review*. Findings were presented at the *8th National Addiction Research Symposium* in Auckland, New Zealand (5 May 2017).

Rychert, M., Wilkins, C. & Witten, K. (unpublished). Are government-approved “legal highs” perceived to be safer and more socially acceptable than alcohol, tobacco and illegal drugs? Findings from a survey of police arrestees in New Zealand. Accepted by the *Drug and Alcohol Review*

## **Abstract**

**Introduction:** In July 2013, New Zealand passed the Psychoactive Substances Act (PSA), which established a legal regulated market for government-approved products containing new psychoactive substances (NPS). One of the aims of the PSA was to separate the market for approved NPS products from unapproved products and illegal drugs.

**Aim:** To explore perceived health risks and social acceptability of government-approved NPS compared to unapproved NPS and other drugs.

**Method:** 834 police arrestees were surveyed about the health risks and social acceptability of regularly using nine drug types, including approved and unapproved synthetic cannabinoids (SC) and “party pills” (PP) under the interim PSA regime. Statistical analyses included fitted ANOVA and logistic ordinal regression models.

**Results:** Approved SC were considered riskier to health than (natural) cannabis, alcohol, approved and unapproved PP, tobacco and ecstasy, but safer than unapproved SC and methamphetamine. Younger participants (16-29) were more likely than older participants (30 plus) to give approved SC a high health risk score. Approved SC were considered less socially acceptable than alcohol, tobacco and cannabis, but more socially acceptable than methamphetamine, unapproved SC and unapproved PP. Frequent SC users were more likely to rate the social acceptability of approved legal SC higher than other drug users. Approved PP received more positive health and social acceptability scores than approved SC.

**Conclusions:** The PSA was partially successful at separating approved NPS from other drugs. High health risk and low social acceptability scores for approved SC may reflect the absence of product testing during the interim PSA market.

## Introduction

A number of studies have associated changes in recreational use of illegal drugs with trends in perceived health risks and social acceptability (Bachman, Johnson, & O'Malley, 1998; Bachman, Johnston, & O'Malley, 1990; L.D. Johnston, 2003). For example, increases in cannabis use among US high school seniors in the 1990s were linked to a decrease in perceived health risks and societal disapproval of cannabis (Bachman et al., 1998), while the opposite was observed with the decline in cocaine use in the late 1980s (Bachman et al., 1990). Similarly, the decline in tobacco use in the second half of 20<sup>th</sup> century has been associated with increased perceptions of tobacco-related health harm (Leidner, Shaw, & Yen, 2015). In the context of illegal drug use, it has been argued that rates of use are more strongly connected with changing perceptions of health risks than with changes in legal status or penalties (Single, Christie, & Ali, 2000). In addition, many argue that legalisation of cannabis for recreational and medical use may lead to reduced risk perceptions and increased social acceptability, which in turn may result in increased use (Hall & Lynskey, 2016a), particularly among adolescents (Hall & Morley, 2015; Hopfer, 2014).

The legalisation of cannabis in a number of US states offers a unique opportunity to investigate the impact of legalisation on perceptions of health risk of a newly legal drug. Findings from empirical studies have been mixed to date. For example, American high school seniors reported some intention to initiate cannabis use (10% of non-cannabis users) as well as intention to use cannabis more often (18% of lifetime cannabis users) if it was legalised (Palamar, Ompad, & Petkova, 2014). It is hypothesised that these intentions arose due to a decrease in perceptions of the health risks of cannabis following legalisation (Estoup, Moise-Campbell, Varma, & Stewart, 2016). Students' intentions to use cannabis post-legalisation were higher among males, younger students (i.e. under 18 years old) and among those whose parents came from high educational backgrounds (Palamar et al., 2014). Another study in Washington found that recent legalisation of recreational cannabis resulted in relatively little change in cannabis-related attitudes or declared likelihood of using cannabis in a sample of adolescents and their parents from low-income families (Mason, Hanson, Fleming, Ringle, & Haggerty, 2015). Parents who had used cannabis in the past expressed more favourable opinions towards cannabis use than those who had never used cannabis and reported increased likelihood of using cannabis post-legalisation (Mason et al., 2015). Cerdá et al. found that perceived harmfulness of cannabis use decreased significantly in Washington post-legalisation (among 8th and 10th graders, but not 12th graders), but no significant differences were found in Colorado (Cerdá et al., 2017). On the other hand, Ghosh et al. reported that youth perceptions of risk decreased following legalisation

of recreational cannabis in Colorado (54% of respondents viewed cannabis as risky in 2013 compared to 48% in 2015) (Ghosh et al., 2017). The relatively small changes in risk perceptions of cannabis post-legalisation may be due to the fact that cannabis use is already well integrated into Western cultures. Accordingly, any changes in cannabis-related attitudes may largely be a reflection of years of “normalisation” rather than due to the establishment of government-regulated markets.

In July 2013, the New Zealand government passed the Psychoactive Substances Act (PSA), which established a legal regulated market for government-approved products containing new psychoactive substances (NPS). NPS are substances designed to mimic the effects of traditional drugs which are not prohibited under the international drug control framework and may be marketed as so-called “legal highs” (Brandt et al., 2014; UNODC, 2013a). New Zealand’s PSA attempts to impose regulatory controls on these products. Under the interim PSA regime, 47 products received government approval to be legally manufactured and sold subject to new retail restrictions on age of purchase (R18), place of sale (only specialised licensed retailers allowed to sell), and advertising (no advertising in major media) (Rychert & Wilkins, 2015a; Wilkins, 2014a, 2014b). Products received interim approval if they had been on the market for at least 3 months before the PSA was passed and had not received any significant adverse event notification. Forty of the 47 approved products were synthetic cannabinoid (SC) smoking blends (Wilkins, 2014b). The remaining products included one SC pill (active ingredient SGT-42) and a range of ‘party pills’ (PP) containing a combination of ingredients commonly used in dietary supplements, such as caffeine, various amino acids, kava, vitamin B and citrus aurantium.

Evidence from other countries show that drug users view SC as an unpleasant alternative to natural cannabis and report more harmful effects from SC than from natural cannabis (Winstock & Barratt, 2013). For example, a survey of 871 police detainees in Australia found that majority of arrestees did not agree with the statement that “SC is safer to use than bush weed or hydro”, with arrestees who had used SC the most likely to say “no” (67%), followed by cannabis-only using detainees (55%) (Macgregor & Payne, 2013). Corazza et al. found that 74% of surveyed students in the UK (n=446) did not consider NPS products safer than illicit drugs and only 11% chose to use NPS because of their presumed safety (Corazza, Simonato, Corkery, Trincas, & Schifano, 2014). However, it is important to note that these perceptions of the risks of NPS were made in environments where NPS are prohibited and there is no government regulation of the manufacture or sale of NPS products.

Consistent with harm minimisation principles, one of the objectives of the PSA regime is to “provide public confidence about the safety profile of the psychoactive substances legally available for sale” and reduce the likelihood consumers will seek out untested products from the black market (MOH, 2012). It has been hypothesised that, as a consequence of new PSA regulations, people are likely to perceive government-approved NPS products as safer and more socially acceptable than other drugs (Wilkins, 2014a).

Accordingly, the aim of this paper is to explore perceived health risks and social acceptability of government-approved NPS products under the interim PSA compared to unapproved NPS, and traditional legal and illegal drugs, and to investigate whether drug use and sociodemographic characteristics influence these perceptions. Specific research questions are:

1. How are the health risk and social acceptability of approved SC and PP viewed in comparison to unapproved SC and PP, and other legal and illegal drugs?
2. Do appreciations of health risks and social acceptance of approved SC and PP vary between different drug user and sociodemographic groups?

## **Methods**

The analysis in this paper utilises data from the New Zealand Arrestee Drug Use Monitoring study (NZ-ADUM) where each year approximately 800 police arrestees are surveyed about their alcohol and other drug use at four central city police stations in New Zealand (i.e. Whangarei, Auckland Central, Wellington Central and Christchurch Central). Interviewing is conducted by civilian research assistants in a private room at the police watch house and confidentiality is guaranteed. Two interview shifts (morning and evening) are completed each day, seven days-a-week, at each watch house during the four months of interviewing. Full details of the NZ-ADUM methodology have been reported previously (Wilkins, Parker, Prasad, & Jawalkar, 2016; Wilkins, Prasad, Parker, Rychert, & Moewaka Barnes, 2016; Wilkins & Sweetsur, 2011). The ethical protocols used in NZ-ADUM have been approved by the Massey University Human Subjects Ethics Committee.

This paper utilises data from 2014 NZ-ADUM wave. From mid-April to the end of July 2014 834 police arrestees were surveyed about their alcohol and other drug use over the previous 12 months. The 2014 interview wave covers the months up to and immediately following the ending of the interim PSA regime in May 2014. The questions on health risks and social acceptability referred specifically to the PSA regime by referring to “approved” and “unapproved” NPS products.

## Measures

### Demographics

A range of demographic measures were collected, including age, gender, employment status, and highest educational achievement.

### Mental health history

Participants were asked if they ever suffered from any mental illness (such as “depression, psychosis, schizophrenia, ADHD, anxiety, conduct disorder”).

### History of substance use

Participants were asked whether they used any of a list of 12 drug types in the past year, including alcohol, tobacco, cannabis, cocaine, heroin, methamphetamine, ecstasy, tranquilizers, LSD, amphetamine, and the two main types of NPS products sold in New Zealand (“party pills” and “synthetic cannabis”), and how often they used each drug type in the past 12 months.

### Perceptions of health risks

Participants were asked to rate the “health risk” of regularly using nine drug types (i.e. alcohol, tobacco, cannabis, ecstasy, methamphetamine, approved SC, unapproved SC, approved PP, and unapproved PP) on a 10-point ordinal scale, where 1= no risk and 10 = extreme risk. They were informed regular use referred to “at least monthly” use. A similar ordinal scale to measure perceived risk of drug use has been used in previous studies (Bachman et al., 1990; L. D. Johnston, O'Malley, Miech, Bachman, & Schulenberg, 2016).

### Social acceptability

Participants were asked to rate how “socially acceptable” it is to regularly use the same nine drug types on a 10-point ordinal scale, where 1 = never acceptable and 10 = always acceptable. As above, the list included “synthetic cannabis” and “party pills” with separate categories for “approved” and “unapproved” types of these products.

## **Analysis**

For the purposes of further analysis, participants were divided into six different mutually exclusive drug user groups: (1) frequent SC users – those who used SC 12 or more times in the last year; (2) occasional SC users – those who used SC less than 12 times in the last year; (3) traditional legal drugs users – those who only used alcohol and/or tobacco; (4) cannabis users – those who used cannabis and possibly alcohol and/or tobacco but no other drugs; (5) ecstasy users – those who used ecstasy and possibly cannabis/alcohol/tobacco; and (6) methamphetamine users – those who used methamphetamine and possibly cannabis/alcohol/tobacco/ecstasy. Participants were also divided into sociodemographic groups based on age (16-29 years old; 30 plus), employment status (employed; unemployed; students), gender (female; male), ethnicity (Maori vs. non-Maori), mental health status (those who had ever suffered mental health illness; those who had never suffered mental health illness) and educational achievement (those with high school education completed and those without high school qualifications).

To assess how approved SC and PP are viewed in relation to the other drugs ANOVA models were fitted. An ordinal response was used for the models since health risk and social acceptability were recorded on a 10 point Likert scale. Contrast vectors were constructed between approved SC and approved PP and the other drugs to investigate any differences in the health risk or social acceptability scores. A logistic ordinal regression model was used to investigate the associations between health risk and social acceptability scores and the types of drug used and sociodemographic characteristics. If drug use patterns or sociodemographic variables were significantly associated with health risk or social acceptability they were investigated further using odds ratios with corresponding p-values adjusted for any multiple comparisons via the Tukey-Kramer method. All analyses were performed in SAS (9.3) and results were deemed significant at  $\alpha=0.05$ .

## **Results**

### **Demographics**

The police arrestee sample was overwhelmingly male, young, of Maori ethnic background, with high unemployment levels, low educational achievement and history of mental illness (Table 9).

**Table 9: Demographic characteristics of police arrestee sample**

	n=834
Male	86%
Mean age (years)	29
Age 16-29	66%
Age 30+	34%
Ethnicity	43% Maori 40% European 13% Pacific 1% Asian
Not completed High School Education	44%
Unemployed	52%
Ever suffered mental illness	36%

**Perceived health risk and social acceptability of approved legal SC and approved legal PP compared to other drugs**

Figure 9 presents the distribution and mean scores of the health risks and social acceptability for all drug types scored. Approved SC were considered riskier to health than (natural) cannabis ( $p < 0.01$ ), alcohol ( $p < 0.01$ ), ecstasy ( $p < 0.01$ ), approved PP ( $p < 0.01$ ), tobacco ( $p < 0.01$ ) and unapproved PP ( $p = 0.01$ ), but safer than unapproved SC ( $p = 0.04$ ) and methamphetamine ( $p < 0.01$ ). Approved legal PP were considered riskier to health than cannabis ( $p < 0.01$ ) and alcohol ( $p < 0.01$ ), but safer than unapproved PP ( $p < 0.01$ ), both approved and unapproved SC ( $p < 0.01$ ) and methamphetamine ( $p < 0.01$ ). There was no difference in perceptions of the health risk of approved PP compared to ecstasy ( $p = 0.29$ ) or tobacco ( $p = 0.91$ ).

In terms of social acceptability, approved SC were considered less socially acceptable than alcohol ( $p < 0.01$ ), tobacco ( $p < 0.01$ ) and cannabis ( $p < 0.01$ ), but more socially acceptable than methamphetamine ( $p < 0.01$ ), unapproved SC ( $p < 0.01$ ) and unapproved PP ( $p < 0.01$ ). There was no difference in perceptions of the social acceptability of approved SC compared to ecstasy ( $p = 0.79$ ) and approved PP ( $p = 0.56$ ). Approved PP were considered less socially acceptable than alcohol ( $p < 0.01$ ), tobacco ( $p < 0.01$ ) and cannabis ( $p < 0.01$ ), but more acceptable than methamphetamine ( $p < 0.01$ ), unapproved SC ( $p < 0.01$ ) and unapproved PP ( $p = 0.02$ ). Again, there was no difference in the social acceptability of approved legal PP and ecstasy ( $p = 0.75$ ) and approved legal SC ( $p = 0.56$ ).

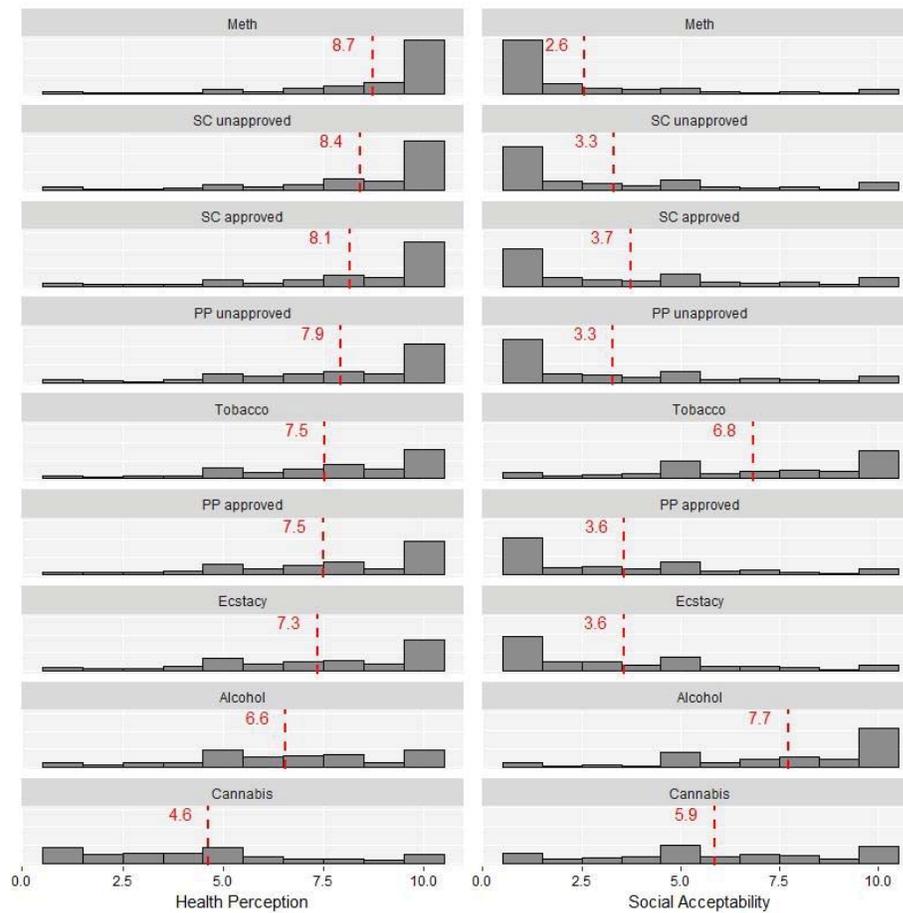


Figure 9: Mean health risk and social acceptability scores for all drugs

### Associations between drug use, sociodemographic characteristics and health and social acceptability score

Younger participants (16-29) were less likely to give approved SC a low health risk score than older participants (30+) (OR=0.590, 0.368-0.947, p=0.03) (Table 10). There were no statistically significant associations between drug user group and demographic variables and the health risk of approved PP.

Table 10: Association between drug use and demographic variables and health risk and social acceptability scores

	Health risk		Social acceptability	
	Approved SC	Approved PP	Approved SC	Approved PP
<b>Drug user groups</b>	p=0.07	p=0.34	<b><i>p&lt;0.01 *</i></b>	<b><i>p=0.01 *</i></b>
<b>Age groups</b>	<b><i>p=0.03 *</i></b>	p=0.36	p=0.22	p=0.14
<b>Employment status</b>	p=0.61	p=0.91	p=0.99	p=0.79
<b>Gender</b>	p=0.11	p=0.18	p=0.39	p=0.59
<b>Ethnicity</b>	p=0.51	p=0.42	p=0.13	p=0.06
<b>Mental health history</b>	p=0.90	p=0.29	p=0.83	p=0.30
<b>Education achievement</b>	p=0.58	p=0.16	p=0.88	p=0.97

\*- statistically significant associations

With respect to social acceptability, the drug user groups were significantly associated with social acceptability of both approved SC and approved PP (Table 10). Occasional SC users were more likely to give approved SC a low social acceptability score than frequent SC users (OR=3.226, 1.473-7.042,  $p<0.01$ ) (Table 11). Users of legal drugs only, cannabis users, and methamphetamine users were also more likely to give approved SC a low social acceptability score than frequent SC users (Table 11). There were no statistically significant associations between the different drug user groups and the social acceptability of approved PP once the tests were adjusted for multiple comparisons (Table 11).

Table 11: Association between frequent SC users and other drug user groups and social acceptability scores

	Approved SC				Approved PP			
	Adj p	Odds ratio	95% Wald Confidence Limits		Adj p	Odds ratio	95% Wald Confidence Limits	
Ecstasy vs frequent SC users	0.07	4.009	0.930	17.286	0.24	3.187	0.707	14.363
Legal drugs only vs frequent SC users	<b>0.03 *</b>	5.332	1.135	25.063	0.09	4.487	0.879	22.903
Cannabis vs frequent SC users	<b>&lt;0.01 *</b>	6.229	1.928	20.132	0.07	3.214	0.960	10.757
Meth vs frequent SC users	<b>&lt;0.01 *</b>	3.611	1.328	9.820	0.26	2.130	0.782	5.804
Occasional SC users vs frequent SC users	<b>&lt;0.01 *</b>	3.226	1.473	7.042	0.09	2.128	0.945	4.785

\*- statistically significant associations

## Summary and discussion

This paper reports perceptions of the health risks and social acceptability of using government approved NPS products during a regulated legal high market by a sample of police arrestees. The police arrestees considered approved NPS products to be riskier and less socially acceptable than legal and most illegal drugs under assessment. Approved SC and approved PP were ranked closer to methamphetamine than to alcohol or (natural) cannabis. Approved PP were generally considered safer and more socially acceptable than approved SC. This more favourable assessment of approved PP compared to approved SC may reflect the actual health risks due to composition of the products, i.e. most approved PP contained low potency herbal ingredients as opposed to potent SC smoking blends.

The high health risk scores for approved SC may reflect the types of SC products approved for sale during the interim PSA regime. A number of New Zealand studies have identified serious health problems and issues of dependency related to the synthetic cannabinoids used during the interim PSA regime, including seizures, psychosis, anxiety, heart palpitations, depression and agitation (Glue et al., 2016; Glue et al., 2015; Macfarlane & Christie, 2015; Wilkins, Prasad, Wong, et al., 2016). Some of the compounds in products approved for the interim PSA regime

(AB-FUBINACA, PB-22) have subsequently been banned in other countries (Drug Enforcement Administration Department of Justice, 2014; *German Federal Narcotics Act*, 2014). The role of media in forming social perceptions about approved NPS products may also have been a factor. In New Zealand, media reporting during the interim PSA regime was described as “sensationalist”, with a focus on negative stories featuring drug dependency and social unrest (Rychert, Wilkins, & Witten, 2017b).

Younger police arrestees (16-29) were more likely than older police arrestees (30 plus) to give approved SC a high health risk score. One explanation for this is that younger participants may have had more knowledge about the SC products through either first-hand experience of use and/or information gleaned from SC using peers, while the older participants’ assessment may have been made solely on the basis of legal status. The police arrestees who were frequent SC users were more likely to view approved legal SC products as more “socially acceptable” than arrestees using other drugs, and this may merely reflect their experience of use and socialisation within peer networks where use is common. However, their perceptions of health risks of approved SC products were no different from other drug user groups. Again, this may be due to their experiences with the problematic products approved during the interim regime.

This study provides a unique insight into police arrestees perceptions of the health risk and social acceptability of government approved NPS products compared to traditional legal and illegal drugs. It is important to note that police arrestees generally have much higher levels of alcohol and drug use than the general population (Wilkins, Prasad, Parker, et al., 2016) and this greater experience may cause them to be more complacent about the risk of substance use than the wider population. On the other hand, more experience may make their assessments more informed and accurate. Police arrestees may also be less trustful of government authority and regulation than the wider public.

Overall, participants made the distinction between approved and unapproved products and it appears that legal approved products were successfully separated from the black market. However, given the high health risk scores and low social acceptability scores for approved NPS products, especially for approved SC products, it is debatable whether the PSA achieved its aim of “providing users with confidence about the safety profile of the psychoactive substances legally available for sale” (MOH, 2012). The limited credibility of the product approval status may be due to the fact that the interim approved products were not tested under the proposed full PSA regime product testing framework which requires toxicology and clinical trials similar to medicines. It has been suggested that the criteria for interim product approval may have been

too liberal (Rychert, Wilkins, & Witten, 2017a). Products approved under the full PSA product testing process may well be viewed by users and the public as safer than many other illegal and legal drugs. The PSA regime has been opened for product applications under the full testing framework since November 2014, but no applications have been made to date.

### **Limitations**

The analysis in this paper has a number of limitations. Firstly, the sample is not a representative sample of the general population or all police arrestees. It is not ethical or safe to interview some arrestees due to intoxication, violent behaviour or emotional distress. Secondly, police arrestees' appreciations of health risks and social acceptability of drug use may be different from the wider general population as discussed above.

### **Conclusions**

This study suggests governmental approval of psychoactive products does encourage users to rate the health risks and social acceptability of approved products differently from similar unapproved products. However, government approval does not suspend users' own critical assessment of the health risk of different drugs and this assessment is made regardless of the legal status. The findings illustrate a complex link between legality of a drug and perceptions of its safety. For example, younger police arrestees were particularly well aware of health risks related to the use of approved SC products. This suggests factors other than legality, e.g. personal experiences with a drug, may be equally important.



## **Chapter 9: The challenge of a ban on animal testing for the development of a regulated legal market for new psychoactive substances (NPS) ('legal highs') in New Zealand: Issues and options for resolution**

This final results chapter investigates future scenarios for the “regulated market regime” under the PSA. As outlined in the literature review (Chapter 2) and other papers published during the course of this PhD, the ban on animal testing for prospective products introduced by an amendment in May 2014 poses a significant challenge to the future of the regime. In this chapter, strategic options to move the regime forward in spite of the ban are developed and evaluated.

The paper comprising this chapter is published in the *International Journal of Drug Policy*. Early findings from this research were also published in *Addiction* as a letter to the Editor (see Appendix K).

Rychert, M. & Wilkins, C. (2015). The challenge of a ban on animal testing for the development of a regulated legal market for new psychoactive substances (NPS) ('legal highs') in New Zealand: Issues and options for resolution. *International Journal of Drug Policy*, 26(12), 1273-1278. Doi: <http://dx.doi.org/10.1016/j.drugpo.2015.08.006>

## Abstract

**Background:** In mid-July 2013, New Zealand passed the Psychoactive Substances Act (PSA) which allowed "low risk" psychoactive products ('legal highs') to be approved for legal sale. In early May 2014, following public protest, the Psychoactive Substances Amendment Act (PSAA) was passed banning animal testing of psychoactive products, potentially making the new regime unworkable.

**Aim:** To investigate strategies to overcome the impasse created by the animal testing ban.

**Methods:** Solutions to the impasse were investigated using 'scenario' and 'stakeholder' analysis. Legislation, parliamentary debates, and regulatory statements related to the PSA and animal testing were reviewed. Strategies to resolve the impasse were discussed with stakeholders including the Psychoactive Substances Regulatory Authority (PSRA) officials, health officials, a legal high industry lawyer, and a leading legal highs manufacturer. This process generated six possible scenarios and five decision-making criteria of key importance to major stakeholders. Scenarios were then evaluated based on feedback from the industry and regulators.

**Results:** The six scenarios were: (1) pragmatic modification of the animal testing ban; (2) waiting until new non-animal test models are internationally accepted; (3) use of non-validated replacement test methods; (4) judicial challenge of the animal testing ban; (5) 'creative compliance' by only presenting human clinical trial results; and (6) philosophical re-conceptualisation of the 'benefits' from psychoactive products. Options 1 and 5 appear to be the most attractive overall solutions. However, both rely on a new political consensus and astute framing of the issues by political communicators. Political decision makers may be happy to accept Scenario 2 which would impose significant delays.

**Conclusions:** A 'failed' pharmaceutical product with psychoactive effects may have the test data required to be approved under Scenarios 1 and 5. Ultimately the pleasurable benefits from psychoactive products may need to be included in the debate.

## Introduction

The enactment of the *Psychoactive Substances Act* (PSA) in New Zealand in July 2013 established the world's first regulated legal market for new psychoactive substances (NPS), ('legal highs') (New Zealand Parliament, 2013a; Wilkins, 2014a). This novel approach to the proliferation of NPS has received considerable international attention as a possible solution to ongoing problems with NPS that could be adopted by other countries (Brandt et al., 2014; EMCDDA, 2015e; Hughes & Griffiths, 2014; Meacher, 2013; Newberry, Wodak, Sellman, & Robinson, 2014; Seddon, 2014; UK NPS Review Expert Panel, 2014). Under the new regime sponsors can gain approval to legally manufacture and sell psychoactive products if they demonstrate through clinical trials that products are "low risk" (New Zealand Parliament, 2013a; Wilkins, 2014a). Approved products would then be sold subject to a range of retail restrictions and other regulations (New Zealand Parliament, 2013a).

Since the passage of the PSA, implementation of the law has proven to be challenging and controversial (see Figure 10). An interim regime was established which allowed a limited number of products available on the market prior to passage of the PSA to continue to be sold subject to new retail restrictions (i.e. R18, no sales from convenience stores, limited advertising) until detailed regulations were finalised (Wilkins, 2014b). However, following ongoing reports of adverse effects from interim licensed products, this transitory regime was brought to an abrupt end by the urgent passage of the *Psychoactive Substances Amendment Act* (PSAA) (New Zealand Parliament, 2014a) on May 6, 2014 (New Zealand Parliament, 2014b).

While the ending of the interim regime was widely viewed as a setback, a potentially more fatal impact of the PSAA was the decision to prohibit the use of animal tests (including tests conducted overseas (New Zealand Parliament, 2014b; PSRA, 2014a)) to assess the risk of psychoactive products. This followed numerous public protests against the harming of animals for the purpose of testing recreational psychoactive products with no therapeutic effects (MOH, 2014f; New Zealand Anti-Vivisection Society, 2014). While work on regulations to implement the full PSA regime has continued, the Psychoactive Substances Regulatory Authority (PSRA) has gone so far as to state that "it is unlikely that a product can be shown to pose no more than a low risk of harm without the use of animal testing"; suggesting the PSA is now unworkable (PSRA, 2014a).

The aim of this article is to investigate strategies to overcome the impasse created by the banning of animal testing for the purpose of pre-market approval of psychoactive products. We identify and critically evaluate six scenarios for the regime based on five criteria of key

importance to major stakeholders, i.e. political decision makers and the legal highs industry. The issue of what role animal testing should play in determining the safety of legal recreational drugs with no therapeutic benefit will be of interest to other countries considering legal markets for NPS, or indeed for other drug types, such as cannabis products.

### **Political background: evolution of the animal testing provisions under the new regime**

The PSA was passed with an overwhelming majority by the New Zealand Parliament on July 11, 2013 (117 ayes to 1 noes) with the one vote against due to the possibility of animal testing (New Zealand Parliament, 2013b). The original provisions of the PSA allowed testing of legal high products on animals, but only if there was no suitable alternative. In combination with the Animal Welfare Act 1999 (New Zealand Parliament, 1999), the PSA provided a framework for animal testing under the new regime (MOH, 2014f). The PSA did not contain a limitation on the animal species allowed to be used for product testing. This led to widespread concerns about the possibility of testing NPS products on companion animals, such as ‘beagle dogs’, and this concern was manifested in public marches and petitions throughout 2013 and into 2014 (MOH, 2014f; New Zealand Anti-Vivisection Society, 2014; New Zealand Parliament, 2014b).

Meanwhile, a political solution was discussed by which animal testing of products would be limited to rodents (MOH, 2014f). The Psychoactive Substances Expert Advisory Committee (PSEAC) subsequently advised Cabinet that animal testing should be extended to include lagomorphs (e.g. rabbits) as “international guidelines require use of one rodent and one non-rodent species for assessment of reproductive toxicity and embryotoxicity” (P. Dunne, 2014; MOH, 2014f). However, in May 2014 the Prime Minister announced a complete ban on the use of animal testing for the new regime, and this change was included in the May amendment legislation. This decision may have been influenced by strength of public opinion on the issue and the impending general election in September of that year (Wodak, 2014).

In subsequent regulatory work on the full PSA regime, the Psychoactive Substances Regulatory Authority (PSRA), the body established by the PSA to oversee the new regime, closely aligned the testing regime for psychoactive products to internationally accepted testing standards for medicines. The International Conference on Harmonisation (ICH) Standards (International Conference on Harmonisation, no date) was designated as the minimum requirement for the approval of NPS products, and the US Food and Drug Administration “Guidance for Industry: Assessment of Abuse Potential of Drugs” (Food and Drug Administration, 2010) as the guide for

investigations into the abuse potential of products (PSRA, 2014a). The Psychoactive Substances Expert Advisory Committee (PSEAC) advised that both these international standards require animal studies for assessing the following aspects of drug safety: “toxicokinetics, teratogenicity, carcinogenicity, reproductive toxicity and addiction potential” (PSRA, 2014a). The absence of validated non-animal models to test for these drug characteristics poses a fundamental issue in providing sufficient evidence to demonstrate low risk of products (Bell, 2015; Rychert & Wilkins, 2015b; Schep et al., 2014). The ‘avoidance of doubt’ provision included in the PSA states that the Regulator “must refuse to approve a product” if it is unable to satisfy itself that the product poses low risk of harm (s. 37(2) PSA). Without full evidence of harms the Regulator will have no option but to reject *all* product approval applications (MOH, 2014f).

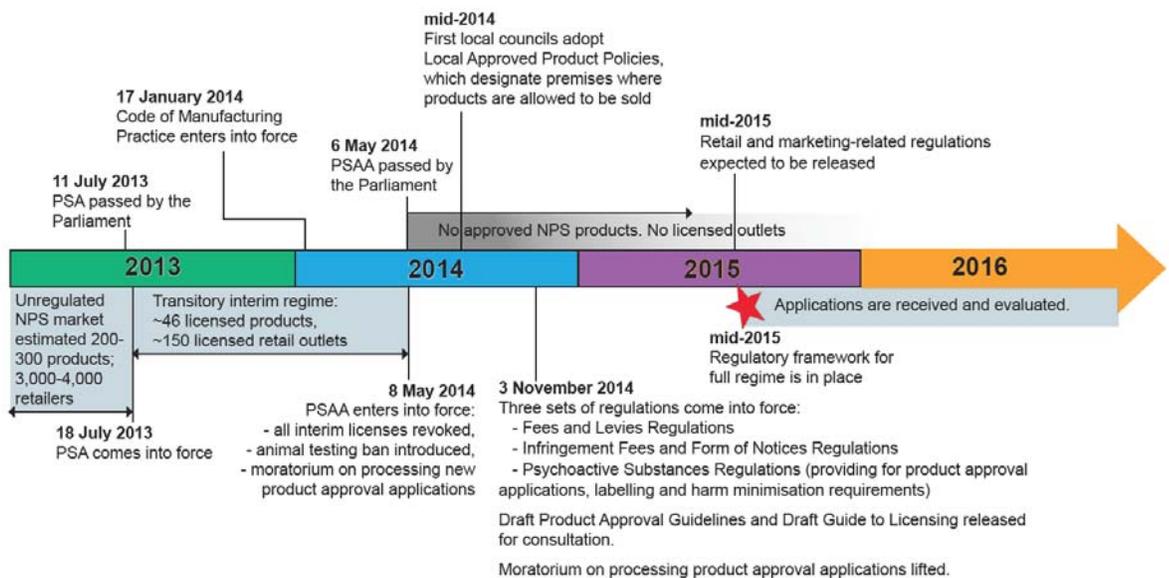


Figure 10: Progress in the implementation of the PSA

## Methods

We used ‘scenario analysis’ to explore options to overcome the impasse created by the animal testing ban on psychoactive products. Scenario analysis was originally developed by the military for strategic analysis (Kahn & Wiener, 1967) and, over subsequent decades, has been applied in company strategic planning (Millett, 1988), public policy decision making (Gambelli, Vairo, & Zanolli, 2010), future forecasting (Bunn & Salo, 1993) and policy analysis in multi-actor settings (Enserink et al., 2010).

A mixed participatory and desk analysis was employed (Bunn & Salo, 1993; Gambelli et al., 2010). The authors reviewed the original PSA legislation and the PSAA from a legal perspective, and

investigated policy documents related to the animal testing issue including transcripts of the parliamentary debates on the PSA, PSAA and the Animal Welfare Amendment Act, regulatory impact statements, and regulatory guidelines. The present impasse, future uncertainties, key driver values and options for resolution were then discussed one-on-one with PSRA officials, health officials, the Medicines and Medical Devices Safety Authority (Medsafe) manager, a lawyer representing the legal highs industry, and a leading legal highs entrepreneur. The legal highs industry and PSRA were determined to be the best informed stakeholders with whom to discuss practical options for the resolution of the impasse within the timeframe before the full regime was made operational (i.e. end of 2015).

This process generated six possible scenarios and five decision-making criteria of key importance to major players (Eden & Ackermann, 1998), i.e. the legal highs industry and political decision makers. The five decision-making criteria were: (1) low financial cost to the industry; (2) certainty of product approval; (3) timeliness; (4) political attractiveness; and (5) favourable public opinion (Table 12). Based on follow-up feedback from the legal highs industry and the regulators we evaluated attractiveness of scenarios to the key players (Bryson, 2004). Each scenario was assessed using a four-point ordinal scale according to how well it fulfilled each of the criteria from the point of view of the legal highs industry and political decision makers respectively (see summary Table 12). For example, with respect to the “low financial cost” criterion, a scenario was given four stars if it was assessed to have a low financial cost to the industry. The “timeliness” criterion was assumed relevant to both stakeholders. A one-star rating for a given criterion suggests the scenario was seriously problematic in that area.

## **Results**

In the following sections each of the scenarios is presented along with a discussion of the likely response to it from the legal highs industry and the political decision makers.

### **Scenario 1: Animal testing ban is revoked or modified**

The most immediate solution to the impasse created by the animal testing ban is to return to the original provisions of the PSA, by which animal testing was allowed unless suitable non-animal testing methods existed. However, such a wholesale reversal may be seen as politically unattractive (Bell, 2015). A number of more subtle modifications of the animal testing ban could be proposed. Firstly, animal testing could be allowed only on defined species, such as rats and rabbits, and only when there are no non-animal testing methods. This approach would exclude

the use of companion animals in product testing, such as dogs. A second option is to allow the use of animal test data previously obtained from the testing of medicines and pharmaceutical products. This would allow applications to be made for medicinal products in development which were proven to have no therapeutic benefit but happen to have a psychoactive effect. In order to reduce the likelihood that this solution might be exploited, it could be limited to tests which were conducted prior to the establishment of the new PSA regime.

A modification of the animal testing ban is likely to be attractive to the legal highs industry as it takes immediate effect and does not impose any additional financial costs (Table 12). The industry could lobby for such a change, but political decision makers may view it as politically risky as the constituents who sympathise with animal rights may be many and vocal. A further amendment to the Act in such a short timeframe may also be viewed as politically undesirable.

### **Scenario 2: Wait for scientific progress on non-animal tests**

The ethical, economic and scientific benefits of alternatives to animal testing (Russell & Burch, 1959) have driven progress in non-animal testing and there has been increased use of replacement methods such as *in vitro* assays and *in silico* tests (AltTOX.org, 2014; Rouquié et al., 2015). However, high predictivity in new models is necessary for their validation and in recent decades only a few *in vitro* studies, mainly focused on local effects or well understood pathways, have been developed sufficiently to be accepted by international regulatory bodies such as OECD and ICH (AltTOX.org, 2014). As a consequence, *in vivo* studies in animals are still central to understanding aspects of compound activity such as pharmacokinetics (Li et al., 2013), reproductive toxicity (Knudsen et al., 2009; Sogorb et al., 2014), carcinogenicity (Annys et al., 2014) and repeated-dose toxicity (Fabulas-da Costa et al., 2013). The complete elimination of animal testing of products is therefore considered a distant goal (Matarese, La Cava, & Horvath, 2012; Rouquié et al., 2015).

Scientific progress on methods of non-animal product testing is the ultimate solution to the impasse. However the current rate of progress in developing alternative methods and their slow regulatory acceptance suggests the impasse may last for decades, essentially preventing the development of any legal highs sector in the foreseeable future. While waiting for scientific progress in this area would be an attractive from a political perspective, the lack of timeliness would undermine the PSA (Table 12).

### **Scenario 3: Applicants use non-validated in vitro test methods**

There is a more proactive alternative to waiting for scientific progress in, and international regulatory acceptance of, non-animal testing. The New Zealand regulator declared itself "willing to consider any and all information as non-animal alternatives to address safety issues" signalling that testing approaches different from those described in international guidelines may be accepted when properly justified, for example in the case of scientific developments, circumstances unique to the product, or the adoption of an acceptable approach which has not been previously considered by the regulator (PSRA, 2014a). In light of this declaration, the industry may choose to provide evidence of low risk with a battery of in vitro tests and in silico models, an approach employed by the cosmetics industry after the EU-wide ban on animal testing of cosmetic products (March 2013) (Vinardell, 2015). However, there remain significant doubts as to what extent replacement alternatives can account for complex impacts on brain function crucial to determining the risks of psychoactive products (Matarese et al., 2012). It has been argued that use of good pharmacological practice, including tests on animals (Mangipudy, Burkhardt, & Kadambi, 2014), should be mandatory in preclinical and clinical studies on NPS (Green & Nutt, 2014; Leach, 2014).

This option would require considerable financial investment by the legal highs industry to determine what non-animal tests could be used, and willingness by the Regulator to accept these alternatives. From the industry perspective, it would be both financially costly and risky (Table 12). From the political perspective, accepting test methods which are not included in the international medicines guidelines may be viewed as accepting lower standards, to the detriment of the health of users (Table 12).

### **Scenario 4: Unsuccessful applicants challenge rejected applications in court**

It could be argued that the animal testing ban provisions included in the PSAA are contrary to the stated purpose of the PSA to "regulate the availability of psychoactive substances (...) and minimise harm to individuals who use psychoactive substances" (s.2 PSA) by creating a legal regulated market for tested low-risk products. This tension may inspire the industry to seek a judicial solution.

In New Zealand judges do not have the authority to declare laws passed by the Parliament invalid because of incompatibility with law of a higher rank or a constitution (Cullen, 2004), but they do have the power to review certain actions of statutory authorities, in particular by referring

administrative decisions back to the original decision-maker with proper directions (LexisNexis, 2015; Taylor, 2014).

Applicants have a number of avenues for challenging the rejection of a product application in court: firstly, by an appeal to the Psychoactive Substances Appeals Committee (PSAC), and secondly by an appeal to the High Court against determination of the PSAC on a question of law (s. 47 PSA). In addition, administrative decisions can be challenged on grounds of ‘illegality,’ ‘procedural impropriety’ and ‘unreasonableness’ in a process of judicial review before the High Court, where reference to natural justice may play a central role (LexisNexis, 2015; Taylor, 2014).

In this ‘judicial review’ scenario applicants would need to go through both the product application process and the court review proceedings. This would be financially costly, involving payment for legal representation, in addition to the NZD 175,000 product application fee (MOH, 2014c). It would also be time-consuming, and risky due to the uncertainty of the judicial outcome (Table 12). It is doubtful whether the industry would deliberately choose this as a primary strategy, but applicants rejected for any reason (including due to animal testing ban) may eventually search for an independent review of decisions and/or regulatory guidelines. A judicial review is likely to be seen as politically undesirable as it may embarrass political decision makers.

### **Scenario 5: ‘Creative compliance’ – human trial data is presented without animal test data**

The ‘creative compliance’ option involves looking at approaches where the required level of product risk data is able to be presented without making an application invalid due to evidence from animal tests. According to the amended legislation, the Regulator ‘must not have regard to the results of any trial that involves the use of animals’ (s. 12(1) PSA) and ‘must not have regard to any information relating to such trial’ (s. 37(3) PSA). In short, the Act states that animals must not be used in trials (both clinical and pre-clinical, including trials conducted overseas) *for the purposes of assessing whether a psychoactive product should be approved*. The animal testing ban can therefore be interpreted narrowly as a ban on the inclusion of animal testing evidence *in the application itself*.

The Regulator requires all human clinical trials to have suitable ethics committee approval and requires all clinical studies to comply with ICH E6R1 Guideline for good clinical practice (PSRA, 2014a). Therefore, outsourcing human clinical trials to countries with loose regulations in order to avoid the animal testing ban is not an option.

The 'narrow interpretation' of the animal testing ban suggests that animals could be used in pre-clinical testing (conducted overseas) as a pre-screening step for the purpose of determining whether human *in vivo* trial is safe and ethical (Brown, 2014; Szalavitz, 2015), as long as this pre-clinical animal data is not included in the final application submitted to the PSRA. It is, however, not clear whether the industry will be able to limit the reference to animal tests in the application, and whether the PSRA will consider evidence from human trials without evidence from prior animal tests as sufficient. The Regulator would essentially be assuming the animal tests had been successful given the human trials had taken place. Some political support may be required to encourage the PSRA to take a sympathetic view concerning applications presented in this manner. Associate Minister of Health and the former manager of the PSRA have both apparently admitted that presenting only human clinical trials data should be enough to make a valid application (Szalavitz, 2015). Finally, legal interpretation of the phrasing of the PSAA, for example what constitutes information *relating* to animal trials, may play an important role.

The 'creative compliance' scenario offers a fairly immediate solution and allows sponsors to 'work within the regulatory framework'. However, it may generate some additional financial costs for the industry and involves risk as it requires political support and the tacit acquiescence of the Regulator, which is not guaranteed (Table 12). A major drawback from the political perspective is that it might be viewed by political opponents and the general public as an attempt to backtrack on previous undertakings to prohibit animal testing of psychoactive products.

### **Scenario 6: Philosophical reconceptualisation of the benefits from recreational psychoactive products**

The regulatory regime for medicines allows animal testing of medical products on the premise that the expected therapeutic benefits of medicines outweigh the losses incurred in terms of animal welfare. Some have argued that there are equivalent benefits from recreational drugs (i.e. pleasure (Ritter, 2014)), and similarly to medicines these pleasurable benefits would offset the harm from animal testing.

While such a philosophical reconceptualisation of the issue may be fairly attractive to both the industry and political decision makers, it may take a long time to achieve political consensus and public acceptance (Table 12).

**Table 12. Evaluation of scenarios to overcome the animal test ban impasse**

	Key criteria	Scenario 1 (modification of the animal testing ban)	Scenario 2 (scientific progress on non-animal testing)	Scenario 3 (use of non-validated methods)	Scenario 4 (judicial review)	Scenario 5 (creative compliance)	Scenario 6 (philosophical reconceptualisation)
Attractiveness to industry (*)	Low financial cost	****	*	*	*	***	*
	Certainty of product approval	***	****	**	*	***	***
Attractiveness to political decision makers (+)	Timeliness	**** / +++++	* / +	** / ++	** / ++	**** / +++++	* / +
	Political attractiveness	++	++++	++	+	++	++
	Public opinion favourability	++	++++	++	+++	+	++

\*\*\*\* - high agreement; \*\*\* - mostly in agreement; \*\* - modest agreement; \* - low agreement

## Discussion and Conclusions

Our analysis suggests that a ‘modification of the animal test ban’ (Scenario 1) may be the most attractive overall solution to the present impasse. However, its success depends on the willingness and ability of political decision makers to communicate such a solution to the public as a compromise towards the wider goal of resolving the ongoing problem with ‘legal highs’. From the narrow perspective of the legal highs industry, ‘creative compliance’ (Scenario 5) may appeal as a timely and cost-effective solution. Again, its success largely depends on some political support and the tacit acquiescence of the Regulator. The major drawback with ‘creative compliance’ is the risk of substantial public and political backlash if it is perceived as a legalistic ‘sleight of hand’. From the narrow viewpoint of a political actor, waiting for ‘scientific progress on non-animal testing’ (Scenario 2) may be viewed as most attractive, which would potentially result in the impasse continuing for years, thereby undermining the regulated legal market approach to these products.

Alongside the implementation of the PSA, a number of other related pieces of legislation and regulation are currently under revision in New Zealand, including the *Food Act 1981*, the *Natural Health and Supplementary Products Bill* (to replace herbal remedies provisions included in the *Medicines Act*) and the *Animal Welfare Act 1999*. As part of the review of the Animal Welfare Amendment Bill a ban on testing of cosmetic products on animals has been proposed (New Zealand Parliament, 2015a). If a compromise were reached on animal testing for cosmetic products, e.g. allowing some form of animal testing, this could conceivably be applied to psychoactive products. Revision of the *Food Act* and laws relating to supplementary dietary

products may also establish acceptable risk and evidence standards which could subsequently be applied to psychoactive products.

A 'failed medicine' which has previously been shown not to have the required level of therapeutic benefit, but which happens to have a psychoactive effect, may already have the required product risk data for approval under Scenarios 1 and 5. The pharmaceutical industry has been engaged in the development of medicinal products containing synthetic cannabinoids such as dronabinol (trade name Marinol) and nabilone (trade name Cesamet). This suggests that similar products may currently exist with related animal and clinical test data at the medical standard. Pharmaceutical companies would have the regulatory experience, laboratory expertise, and capital funding to operate within the proposed psychoactive substances product testing regime.

The debate on animal testing of any consumer product draws on the principles of cost-benefit analysis, i.e. animal testing is only allowed if perceived benefits outweigh losses in terms of animal welfare. Hence, animal testing is accepted for medicines, but increasingly prohibited in safety assessments of consumer products such as cosmetics or detergents. The regulatory regime for NPS in New Zealand is focused on the benefits of creating a regulated market for legal highs by "reducing harm to individuals" (s.2 PSA). Other possible benefits of a regulated market for low risk psychoactive products such as pleasure (Ritter, 2014), performance enhancement (Reuter, 2011) and psychological wellbeing have been ignored in the policy debate. Consideration of these benefits may eventually need to be addressed by policy makers and the public (Moore, 2008) in order to ensure the safety of legal recreational drug products and make a legal market for recreational drugs workable.

We acknowledge a number of limitations with our analysis (for discussion about limitations of forecasting and scenario methods at large see (Bunn & Salo, 1993; Makridakis, 1981; Makridakis & Taleb, 2009). Firstly, the political landscape is complex and continually shifting, and compromises on other pieces of legislation, for example the *Animal Welfare Amendment Bill*, may facilitate progress on the animal ban on psychoactive products. Second, our assessment of the scenarios was based on the stakeholders' appreciation of the risks and opportunities created by each. Finally, we discussed the impasse with the existing stakeholders, i.e. people from the existing legal highs industry and regulators. Other stakeholders, with different capabilities and interests, such as an international pharmaceutical company, may decide to enter the debate and pursue a different solution.

## **Chapter 10: Discussion and conclusions**

### **10.1 Synthesis of findings**

The aim of this thesis has been to critically analyse the PSA and its implementation process. The analysis utilised policy documents and legislation, interviews with key informants, and data from an annual survey of police arrestees. The findings presented in the previous chapters illustrate the complexities of successfully designing and implementing a regulatory response to NPS and highlight the uncertainties about the impacts of new laws designed to regulate the legal market for recreational drugs.

This chapter presents a synthesis of the research findings and discusses implications of this research, including recommendations for future implementation. In Section 10.2.1, issues experienced during the implementation of a regulated legal market for NPS in New Zealand are compared with issues in three new regulatory regimes for cannabis recently implemented overseas (Colorado, Washington and Uruguay). Section 10.2.3 then proceeds to propose 13 recommendations for the future implementation of the PSA in New Zealand. The chapter concludes with a discussion of research strengths and limitations and outlines areas for future research.

#### **10.1.1. Identified challenges with implementing the PSA during the “interim regime”**

At the initiation of this PhD study, understanding of issues experienced with the implementation of the PSA was limited to anecdotal media reports of adverse effects and health problems related to interim approved products, and social disruption around interim retail outlets and public protests. Chapters 5, 6 and 7 contain an in-depth analysis of issues which contributed to the decision to end the interim regime in May 2014, including challenges with: (1) monitoring the safety of interim approved products; (2) establishing and monitoring the retail network; (3) controlling the legal high industry; (4) commercialisation of the market; (5) the slowness of developing regulations; and (6) policy communication and local community opposition.

##### ***Monitoring safety of interim approved products***

Chapter 5 investigated issues related to managing the safety of products approved for sale on the interim PSA regulated market. Identified problems included the high number of products approved for the interim regime and their harmfulness. The interim market was dominated by strong SC smoking blends, which, in retrospect, received criticism from a number of the interviewed KIs (Chapter 5), including some from the LH industry. Industry actors observed that

potentially “safer” lower strength products could not compete with the stronger SC smoking blends approved for the interim market. The system for withdrawing interim approved products which were subsequently found to be harmful was also criticised for its limited responsiveness. The limited availability and quality of data on adverse events, which were at the core of the system design, were identified as some reasons for the slowness of the “approval revocation” process (Chapter 5). There was also criticism of the lack of engagement and awareness among health professionals of the system for reporting adverse effects from approved products.

### ***Monitoring retail outlets***

In terms of the retail environment during the interim regime, identified challenges included monitoring compliance of interim licensed retailers with the new PSA regulations, primarily enforcing the sale of approved products to R18 only (Chapter 6). Other retail behaviours identified by KIs as problematic included the operation of shops during late night hours (as there are no legal provisions limiting hours of operation) and discounting of product prices (facilitated by the lack of price control provisions in the PSA) (Chapters 6 and 7). Many KIs claimed that the reduction in the number of shops under the interim regime (around 150 licensed retailers under the PSA compared to 3,000-4,000 unlicensed shops selling NPS pre-PSA) concentrated a large number of customers at licensed shops, which increased the visibility of shops and related social nuisance.

### ***Controlling the legal high industry and market commercialisation***

KIs from the industry identified that targeting young and low income customers and price cutting were among business strategies adopted by the retailers and product sponsors in response to increasing commercialisation of the market (Chapter 7). While local government authorities were given the power to further limit the operation of retail outlets in their district by developing Local Approved Product Policies (LAPP), there were significant delays in developing these policies due to general opposition to the regime (Chapter 6). The legal high industry attempted to implement self-regulation measures during the interim regime, but these proved insufficient to counteract problems with commercial competition among retailers and product sponsors (Chapter 7).

### ***Slowness of developing regulations for the full PSA regime***

The slowness in developing and implementing official government regulations for the full PSA market also received criticism (Chapter 6). For example, the finalisation of the product testing regime was projected to take no more than six months and be completed by the end of 2013 (MOH, 2014f). As it turned out, the Draft Product Approval Guidelines were released in

November 2014, i.e. six months after the interim regime had been ended by the Psychoactive Substances Amendment Act (PSAA). The only regulatory instrument that entered into force during the interim regime was the Code of Manufacturing Practice (January 2014). KIs explained that resource limitations and an underestimation of the scale of the policy and related workload were some of the reasons for these delays.

### ***Communication about the PSA and community opposition***

The increasing public opposition to the PSA regime emerged in response to problems with retail outlets in local communities and the products allowed on sale. The KIs explained further that the growing opposition to the PSA was the result of a lack of clear policy communication about the aims of the PSA, both before and during the implementation process (Chapter 6). For example, the analysis of parliamentary debates on the Psychoactive Substances Bill (Chapter 2) shows the PSA was seen as a legislative measure for imposing “a deliberately high bar”, and one speaker supported the Psychoactive Substances Bill in the hope “it will send them [the industry] out of business”. This illustrates gaps in understanding of the PSA, even by politicians involved in its enactment. Evidence from written public submissions also supports KI claims that the public lacked understanding about the new approach (Chapter 2). For example, seven out of 72 written submissions from the public (non-institutional, individual submitters) expressed their support for the Psychoactive Substances Bill under the wrongful understanding that it intended to impose a total ban all “legal highs”.

Coupled with the pressure of a looming national general election, the above challenges triggered the government’s withdrawal of all interim product approvals and interim licenses to sell with the passage of the PSAA in May 2014, thus ending the interim regime. This has been widely viewed as a significant setback to the PSA implementation. However, the effectiveness of a “regulated market” response to NPS should not be judged based on the ending of the interim PSA regime, as none of the interim approved products were tested as envisioned in the PSA (i.e. toxicology and clinical trials). Further, the relevant systems to monitor the market were not fully developed at the time the interim PSA market was operating.

### **10.1.2. Critique of the PSA policy process**

Many key informants interviewed for this research attributed the issues identified with the implementation of the PSA to constraints on time, resources and expertise, questioning the process by which the PSA was drafted, adopted and implemented.

The PSA policy process differed from a standard legislative process in several instances, including a shorter Select Committee stage, a shorter public consultation time frame, and the amendment in May 2014 (PSAA) being passed “under urgency” – with no Select Committee stage at all (New Zealand Parliament, no date). The shortened parliamentary process for the Psychoactive Substances Bill (PSB) was officially explained by the fact that temporary bans (TCDNs) previously imposed on 33 NPS compounds were about to expire (New Zealand Parliament, 2013b). Passage of the amendment to the PSA (PSAA) under urgency was officially justified by on-going “harms evidenced with the products” (MOH, 2014f). While the impact of these procedural changes on the final shape of the PSA and its successful implementation remains unknown, it seems that the principles of evidence-based policymaking may have been compromised.

Some details of the regulatory regime did not receive enough attention during the drafting stage of the PSB and they subsequently turned out to be problematic. For example, the issue of animal testing, which was considered “not relevant to the purpose of the Bill” during the Select Committee stage (New Zealand Health Committee, 2013), now poses a significant challenge to the successful implementation of the full PSA regime (Chapter 9). MOH officials expressed their concerns in relation to the PSAA being passed under urgency, stating that “the pressure of time has not allowed [them] to confidently measure the impacts of this proposal on people who use [psychoactive products], on industry and on government and community agencies” (MOH, 2014f).

In terms of stakeholder engagement, the policy development benefitted from targeted consultations and a public submissions process (albeit in a shortened time frame). However, some key stakeholders to the PSA, such as local councils responsible for development of the Local Approved Product Policies (LAPPs), explained their opposition to the new regime arose due to the lack of targeted consultations during the drafting stage of the PSB (Chapter 6). The fact that powers given to local councils via LAPP provisions were not included in the initial drafts of the PSB, but were only added following the public consultation stage, further complicated the engagement process. Similarly, interviews with KIs revealed that some medical professionals had limited knowledge about their role in the regime, which may have undermined the speed and effectiveness of the product ‘safety monitoring’ system during the interim regime (Chapter 5). Improved stakeholder engagement was needed to ensure that clinicians reported adverse events from interim approved products to better inform regulatory decision-making.

Finally, as discussed in Chapter 7, the role of the legal high industry in the policy process was not clear and transparent. While written submissions from the industry organisations and

businesses are publicly available, the extent of targeted consultations with industry actors and influence of their views on the final shape of the PSA and related regulations are not entirely clear. A couple of KIs expressed concerns about the lobbying influence of the legal high industry on the policy processes and this claim requires more supporting investigation (Chapter 7). Given that the legal high industry was actively lobbying for policy change to a regulated market approach and had a clear monetary interest in industry-friendly regulation (Chapter 7), greater transparency in communications between government officials and the commercial stakeholders was needed. The rules for engagement with the industry should also be articulated. One possible approach is to adopt rules similar to those set out in the Framework Convention on Tobacco Control (art. 5.3), under which the industry is excluded from any policy-making processes (Chapter 7).

### **10.1.3. Critique of the PSA legislation**

The objective of the PSA, as defined in s. 3 of the Act, is to “regulate the availability of psychoactive substances in New Zealand to protect the health of, and minimise harm to, individuals who use psychoactive substances”. The second part of the aim referring to the protection of health was only added to the draft PSB following the public consultation process (New Zealand Health Committee, 2013) and calls from many submitters for a focus on harm reduction principles (Chapter 2, s. 2.2.1.2). The stated public health focus of the PSA is reflected in many provisions of the law, primarily in the requirement to prove “low level of risk” before a product is allowed on the market, the restrictions on retail sale, advertising and manufacturing, and the delegation of PSA implementation to an agency situated within the Ministry of Health.

The interviewed KIs, however, identified some gaps in the legislation which may need to be addressed to more closely align the PSA with the intended public health principles. They pointed to the lack of a price control mechanism and the lack of provisions for consumer education. The former omission may have facilitated “price wars” between market operators during the interim regime (as discussed in Chapter 7), and the latter may have added to the on-going reports of harms from interim approved products due to harmful patterns of use. Some other PSA provisions criticised by KIs, such as the legislative criteria for approval of interim products, have already been repealed as part of the ending of the interim regime in May 2014.

Interestingly, most KIs were not concerned about the personal possession offence included in the PSA (s. 71, 74 PSA), under which a police officer may serve an infringement notice (i.e. on-the-spot fine) to a maximum value 500 NZD, if they observe, or “have reasonable grounds” to

believe, that a person is in possession of an unapproved psychoactive substance. Most KIs were not concerned with the ideological debate around state paternalism vs. individual autonomy, but rather accepted this measure may have some preventative or educative value. If this “therapeutic intervention” intention of enforcement is to be realised, then resources are needed for education and rehabilitation programmes aimed at the specific group of NPS users, who are considered to be administrative offenders under these provisions.

The process of developing the regulatory framework for the regime continued during the course of this PhD. For example, in April 2016 the PSRA released regulations regarding online sale of approved products. They established a simple method of remote age verification by requiring prospective purchasers to declare, “by ticking an on-screen box”, that s/he is 18 years of age or over (MOH, 2016). This online method of age verification could be improved by requiring corroborating official verification of age such as a driver licence or through the REALME identity verification service run by the New Zealand Department of Internal Affairs. A careful evaluation and weighing of privacy issues against the public health benefits would be needed if this is to be implemented. Given the problems identified by KIs with the enforcement of age of purchase regulations at physical LH retail outlets during the interim regime (Chapter 6), there is reason to believe that monitoring compliance of online retailers with the age of purchase requirement may prove challenging.

The PSA provisions which turned out to be particularly controversial during the implementation process and received a lot of international attention were the legal definition of a “psychoactive substance” (s. 8, 9(1) PSA) and the prohibition on the use of animal testing for the purpose of assessing the safety of products (s. 12(1) PSA). The former is central to the ongoing international debate about difficulties with operationalising legal definitions of “psychoactivity”, where academics have criticised definitions of “psychoactive substance” as too broad, creating potential difficulties with enforcement (Barratt, Seear, & Lancaster, 2017; Reuter & Pardo, 2017; Stevens et al., 2015). The ban on the animal testing of products has wider implications for the future of the PSA regime, as product sponsors cannot provide the required evidence of low risk without animal testing. Chapters 4 and 9 focused on these issues.

Chapter 4 investigated how products with psychoactive properties are categorised under different pieces of legislation in New Zealand (e.g. the PSA, MODA, Medicines Act, Food Act etc.). I took a pragmatic approach to studying the definition of “psychoactivity” and investigated how it is applied in practice. This is because I accept that broad definitions of certain legal concepts are not unusual. For example, there has been an extensive academic debate on the legal

definition of “terrorism” (Hardy & Williams, 2013; Zeidan, 2003), with critics warning that too broad a definition *could* criminalise investigative journalism (Harris, 2014). Chapter 4 concluded that the legal status of some products with psychoactive properties may be uncertain due to legislative overlap. For example, kava (*Piper methysticum*), a psychoactive plant traditionally used in Pacific cultures, may be categorised as a food, a dietary supplement, a herbal remedy or a psychoactive substance – with implications for its legal status. The problem of multiple classifications could be resolved by developing clear regulatory rules and guidelines. For example, the amount of active ingredient used in a product could be used to differentiate between “psychoactive products” and “dietary supplements”, with products containing very low levels of active psychoactive ingredients considered “dietary supplements” rather than “psychoactive products”. A categorical rule could also be formulated to clarify the status of borderline products. For example, under a “rule of doubt” any product would be considered to fall under the psychoactive regime (rather than dietary supplement/food or herbal remedy regime) if it produces “discernible impairment” in users. During the course of this PhD, the PSRA published a list of plants exempted from the PSA regime with the aim of more clearly categorising certain products of herbal or natural origin. I provided critique of this approach and the published list in a letter published in *Addiction* (Rychert & Wilkins, 2017) (see Appendix H).

Finally, Chapter 9 analysed the legal provisions which introduced a ban on testing of prospective psychoactive products on animals. The analysis adds to the current debate by proposing a number of pragmatic solutions to move the regime forward despite the ban. It concludes that a change to legislation (or its interpretation) may be necessary, for example by allowing the re-use of pre-existing animal trial test results. A ‘failed pharmaceutical’ product with psychoactive properties may have the data required for regulatory approval under this scenario. Without causing further harm to animals, this approach would be consistent with the current acceptance of animal testing in pharmaceutical research, which is rooted in the utilitarian arithmetic of harms vs. benefits (Foëx, 2007).

#### **10.1.4 Social perceptions of the regulated market approach to NPS**

The uncertainties about the health and social impacts of regulating access to legal recreational drugs are a prominent theme in the academic literature on the legalisation of cannabis, with most analyses focusing on (public) health impacts specifically (Caulkins & Kilmer, 2016; Hall & Lynskey, 2016b; Hall & Weier, 2015; Pacula et al., 2014). This PhD investigated social perceptions of regulating NPS, including perceptions of the health risk and social acceptability of approved NPS products (Chapter 8), public support for the PSA regulatory regime (Chapters 2 and 6), and

the role the popular media played in shaping public perceptions of the implementation of the PSA (Chapter 6).

Social attitudes towards using approved “psychoactive products” were examined in-depth in Chapter 8. Police arrestees interviewed for the NZ-ADUM study generally considered using “legal highs” approved under the interim PSA to be more of a health risk and less socially acceptable than using alcohol, tobacco and many illegal drugs. Overall, approved synthetic cannabinoids (SC) and approved party pills (PP) were ranked closer to methamphetamine than to alcohol or (natural) cannabis, and approved SC received more negative opinions than approved PP. The high health risk and low social acceptability scores for approved SC may reflect problems with the assessment of the products approved for the interim PSA market (as indicated by KIs and discussed in Chapter 5).

One of the objectives of the PSA regime was to “provide public confidence about the safety profile of the psychoactive substances legally available for sale” and reduce the likelihood consumers will seek out untested products from the black market (MOH, 2012). It was hypothesised that, as a consequence of the new PSA regime, people may perceive government-approved “legal highs” as safer and more legitimate than other drugs (Wilkins, 2014a). Overall, participants of NZ-ADUM study made the distinction between approved and unapproved products and it appears that legal approved products were successfully separated from the black market during the interim regime (Chapter 8). However, given the high health risk scores and low social acceptability scores for approved legal highs, especially for approved SC products, it is debatable whether the PSA achieved its aim of “providing users with confidence about the safety profile of the psychoactive substances legally available for sale”.

The role of media in forming social perceptions about approved “legal highs” is also relevant. As discussed in Chapter 6, KIs described media reporting during the interim regime as “sensational”, with a focus on negative stories featuring drug dependency and social unrest. The media reporting may have added to the negative perceptions about interim approved products and community opposition to retail outlets for approved products. Analysis of public submissions to the PSA (Chapter 2) and the evidence from opinion polls published in the New Zealand media (Chapter 6) shows that public support for the PSA regime was declining towards the end of the interim regime. This may reflect a revision in public support for drug legalisation once people are faced with real-world legal drug regimes, indicating the need to continue to monitor public support for drug law reform to track changes in support as reforms are implemented.

## 10.2 Research implications

### 10.2.1 Comparison of the PSA and cannabis law reforms in Colorado, Washington and Uruguay

This section brings together findings from this PhD research on New Zealand's response to NPS and the literature on the implementation of cannabis law reforms in Colorado, Washington and Uruguay in order to draw lessons for other countries. The three cannabis law reform jurisdictions were chosen as the most relevant case studies as they are most advanced in the process of implementing drug law reforms.

In the last four years a number of jurisdictions have implemented cannabis law reforms to legalise and regulate the use, sale and manufacture of cannabis. In November 2012, the US states of Washington and Colorado legalised the commercial sale of recreational cannabis (Hall & Lynskey, 2016a; Roffman, 2016). In December 2013, Uruguay became the first country in the world to legalise the regulated sale of recreational cannabis on a national level (Kilmer & Pacula, 2016). In 2014, two more US states (Alaska and Oregon) voted in favour of legalisation and regulation (Hall & Lynskey, 2016a). In November 2016, another four US states (California, Nevada, Maine, and Massachusetts) followed suit (Subritzky, Pettigrew, & Lenton, 2017). The government of Canada also made a significant step towards cannabis law reform with the establishment of the Task Force on Marijuana Legalization and Regulation in June 2016 (Task Force on Cannabis Legalization and Regulation, 2016a, 2016b). Other jurisdictions considering drug law reform have the opportunity to learn from implementation of cannabis law reforms in these countries and New Zealand's experience with the establishment of a regulated market for "psychoactive products".

Among the above-mentioned examples of "commercial drug markets", New Zealand was the first to commence regulated sale of recreational products (May 2013), followed by the opening of the first shops selling recreational cannabis in Colorado (January 2014) and Washington (July 2014) (Figure 11). By the time Uruguay opened the register of home growers (August 2014), one of three modes of accessing cannabis under the new cannabis legislation, New Zealand's interim PSA regime had already come to an end.

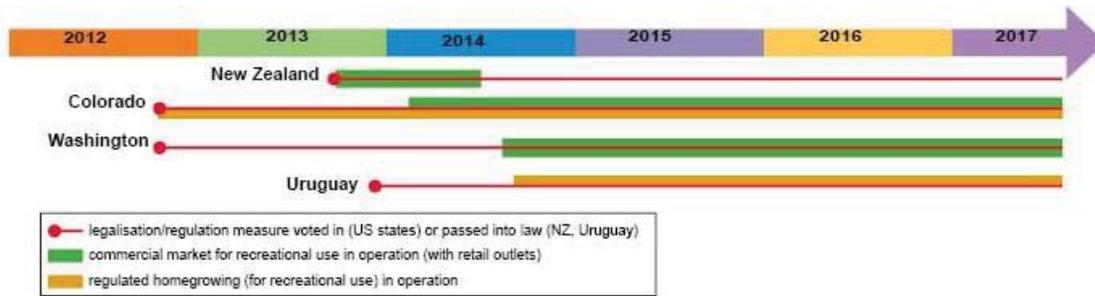


Figure 11: Implementation timeline of “regulated drug market” law reforms in NZ, Colorado, Washington and Uruguay.

Table 13 compares selected issues in the design and implementation of regulatory responses to recreational drugs adopted in New Zealand, Colorado, Washington and Uruguay. The comparison shown in Table 13 covers three aspects of drug policy reform: (1) the organisational and legal context (i.e. the level of drug reform law and government agency responsible for implementation of the law); (2) policy content (i.e. basic elements of regulatory regime defined in the legislation, e.g. how the drug can be legally sourced, what stages of production require state/government licensing, legal restrictions on sale, use, advertising and prices); and (3) the implementation process (i.e. processes adopted in implementation of laws and issues experienced, e.g. parliamentary process adopted in passing drug reform laws, time frame for implementation and major challenges).

**Table 13: Comparison of selected issues in design and implementation of regulatory responses to recreational drugs in NZ, Colorado, Washington and Uruguay**

	"Psychoactive products" regime	Recreational cannabis regimes			
	NZ	Colorado	Washington	Uruguay	NZ
Organisational and legal context	Level of law	National law PSA 2013	State constitution (art. 18, s. 16) (conflict with federal law)	State law (provisions in Chapter 69.50 Revised Code of Washington RCW: Uniform Controlled Substances Act) (conflict with federal law)	National law Ley 19.172
	Government agency	PSRA (MOH)	Marijuana Enforcement Division (Department of Revenue)	State Liquor and Cannabis Board	Institute for the Control and Regulation of Cannabis (Instituto de Regulación y Control del Cannabis, IRCA)
Policy content	Legal access channels	Licensed retailers	Licensed retailers, Home-growing for private use (up to six plants, three in flower)	Licensed retailers	Licensed pharmacies, Home-growing for private use (up to 6 plants / 480 grams) Registered clubs
	Licensing	- Products - Retailers - Manufacturing - Import - Research	- Retailers - Cultivators - Manufacturers - Testing facilities	- Retailers - Producers and processors (i.e. cultivating and manufacturing)	- Retailers (i.e. pharmacies) - Cultivating - Manufacturing - Club members (users)
	Price control measures	GST only (general sales tax)	15% excise tax on cannabis products (+10% sales tax)	Retailer pays excise of 37% (+state and local sales tax) on cannabis products	"variable fee"
	Education and prevention provisions	No mention of prevention and education specific to the use of approved products in NZ laws	No mention in the main reform law, but Colorado Revised Statute (§ 25-3.5-1001 through 25-3.5-1007) requires implementation of education, public awareness and prevention messages for retail marijuana	Yes (see Initiative 502, part 4, s. 28, and RCW 69.50.540 which requires establishment of marijuana prevention and public health programs)	Yes (to be integrated into public education system; art. 9 Ley 19.172)

Policy content	User and sale restrictions	R18, sale limits ("no more than 2 products at a time" – Psychoactive Substances Regulations 2014)	R21, purchase and possession limits (up to 1 oz (28.5 g))	R21, purchase and possession limits (up to 1 oz (28.5 g))	R18, registered in national database (must be citizen or resident for min. 2 years), monthly limits on purchase 1.4 oz (40 g)
	Delegation of power to local authorities	Yes – Local Approved Products Policies can restrict location of licensed retailers	Yes – local authorities may enact regulations on time, place, manner, number of retailers in their localities (s. 16, point 5)	Not in the main law. But Attorney General Opinion confirmed cities and counties can ban retailers.	No.
	Advertising	Regulated, allowed at "point of sale" but prohibited in mainstream media	Regulated, e.g. refrain from advertising on tv and radio, unless there is reliable evidence that no more than 30 percent of the audience is reasonably expected to be under the age of 21. (Permanent Rules Related to the Colorado Retail Marijuana Code)	Regulated, e.g. max. two signs identifying licensed retail outlet (Washington Administrative Code WAC 314-55-155)	All forms of advertising, direct and indirect, prohibited (art. 11 Ley 19.172)
Policy process	Who initiated policy change?	Parliament	Citizen initiative ("Amendment 64")	Citizen initiative ("Initiative 502")	Parliament
	Legislative process	Shorter Select Committee (May 2013)	standard	standard	standard
	Public support at the time of change	Unknown (from analysis of public submissions from individual citizens (Chapter 2): 50% support, 32% oppose)	55% support, 45% oppose	56% support, 44% oppose	Opinion polls: ~30 support, ~60% oppose, 5-10% don't know
	How long from the law to the first shop?	same day (July 2013)	1 year 2 months (Nov 2012 - Jan 2014)	1 year 8 months (Nov 2012 – Jul 2014)	8 months – home growers; 10 months – clubs; no pharmacies since Dec 2013
	Major political changes during implementation?	Ass Minister of Health Peter Dunne out of office between June 2013 and January 2014	No mention in academic literature	No mention in academic literature	President José Mujica stepped down from office March 2015
	Present challenges	Animal testing ban	Product quality testing (purity, edibles - potency), monitoring impacts, industry impacts	Products quality testing (purity, edibles - potency), monitoring impacts, industry impacts	Opposition from pharmacists; reluctance to register as a user

Data compiled through legal research, review of academic literature and reading of policy documents (Colorado Department of Revenue, 2013; Cruz, Queirolo, & Boidi, 2016; EMCDDA, 2016b; Hall & Lynskey, 2016a; Roffman, 2016; Room, 2014; Rychert & Wilkins, 2015b; Subritzky et al., 2017; Walsh & Ramsey, 2015)

New Zealand's PSA regime differs from other jurisdictions with respect to the drug products potentially allowed on the commercial regulated market (i.e. various new psychoactive substances vs natural cannabis only). Further, when first introduced, the New Zealand regime aimed to regulate the previously unregulated "legal high" market, while reforms in Colorado, Washington and Uruguay legalised cannabis which had previously been illegal for recreational use. Another notable difference, inherent to the nature of the NPS problem and ideas behind the PSA, is that the regulatory regime in New Zealand operates for specific *products* and not for *a substance* (cannabis in Colorado, Washington and Uruguay). Approval is granted for each separate product under the PSA, which means that the formulation, including composition and strength, can no longer be modified once approval for the product is granted. This focus on approval of products comes with certain advantages (such as greater regulatory control over the market) and disadvantages (e.g. may require greater regulatory resources for processing product applications and monitoring the products).

In terms of specific market control measures, there are some common features of laws across the jurisdictions, including the establishment of a legal purchase age (which matches the legal alcohol purchase age in all jurisdictions) and the licensing of retailers and manufacturers – both standard provisions in alcohol regulation. All jurisdictions go beyond the standards of regulation for purchase of alcohol and tobacco as they have established maximum purchase or sale limits on newly regulated drugs, i.e. monthly limits on cannabis purchase in Colorado, Washington and Uruguay, and "per transaction" limits on sale of recreational products in New Zealand (introduced after the ending of the interim regime (MOH, 2014d)). This is an interesting difference, indicating extra responsibility for avoiding heavy consumption has been placed on retailers of new legal recreational drugs.

In contrast to other jurisdictions, New Zealand's PSA lacks provisions for price control and education or prevention strategies for approved recreational products. In terms of advertising, Uruguay prohibits all forms of advertising cannabis, while New Zealand, Washington and Colorado have imposed regulations on allowed modes of advertising. For example, New Zealand only allows advertising of approved products from "place of sale" (including internet websites approved for selling products) but prohibits advertising in all mainstream media. Colorado, on the other hand, mandates that the industry shall refrain from advertising on the radio and television unless there is reliable evidence that no more than 30 percent of the audience for the programme is reasonably expected to be under the age of 21 (Colorado Department of Revenue,

2013). This approach follows the voluntary regulation previously adopted by the alcohol industry in Colorado (Colorado Department of Revenue, 2013).

In terms of policy implementation, countries with a top-down approach to drug law reform (i.e. parliament-initiated policy change as opposed to grass-roots “citizen initiatives”), i.e. New Zealand and Uruguay, experienced community opposition to the new legal drug markets and this has been defined as a significant challenge in the implementation process (Rychert et al., 2017b; Walsh & Ramsey, 2015). In New Zealand, some of the community opposition has been explained as due to the lack of policy debate around the reform before and during its implementation. In Uruguay, the public remained sceptical about the reform despite civil society and government efforts to increase support (Walsh & Ramsey, 2015). Changes in political leadership among those initiating legislative reform have also proved challenging. For example, Peter Dunne, who introduced and lobbied for the PSB in New Zealand (New Zealand Government, 2013b) was replaced as Associate Minister of Health at a critical time in the legislation’s enactment and implementation. The politician who assumed his functions publicly protested against interim licensed retail outlets and openly disagreed with the PSA regime (A. King, 2014). In Uruguay, the retirement of cannabis law reform leader President José Mujica is considered a significant factor contributing to delays in implementing law reform (Martínez, 2016). Public support for cannabis law reform in Uruguay was found to be associated with public approval of the President’s performance (Cruz et al., 2016). Cruz et al. (2016) concluded that had President Mujica been less popular, the resistance to cannabis legalisation may have been (even) higher and the policy process more complicated.

Another common challenge experienced during the implementation processes related to the delegation of regulatory powers under new regimes to local bodies and communities, and the need to clarify these powers in subsequent legal opinions. For example, in Washington State a number of cities and counties banned legal cannabis retailers. Following a period of uncertainty, the Attorney General ruled that local governments did indeed *have* the right to ban cannabis-related businesses from their jurisdictions (Roffman, 2016). Similarly, Hamilton City Council in New Zealand effectively banned legal high stores from their district by imposing very broad control measures in their Local Approved Product Policy (LAPP) (see Chapter 6). Hamilton’s LAPP was challenged in court by the industry, but following the ending of the interim regime the case was dropped (see decision in: *The Star Trust v Hamilton City Council* [2016] NZHC 821 [28 April 2016]).

Jurisdictions where the commercial industry were involved in the establishment of the market, i.e. New Zealand, Washington and Colorado, experienced problems with industry influence during the process of developing and implementing legislation and regulations (Lenton, 2014; Rychert & Wilkins, 2016a; Subritzky, Lenton, et al., 2016). For example, in Colorado the cannabis industry was reported to have “pressured regulators to weaken pesticides regulations” (Subritzky, Lenton, et al., 2016). In New Zealand, the extent of industry consultation and lobbying with government officials on the PSA is not well documented, but issues with industry lobbying and commercialisation of the market were explored in Chapter 7. Questions were raised in the popular media about a possible conflict of interest between the Associate Minister of Health and his son, a lawyer who represented the legal high industry (Kirk, 2014).

### **10.2.2 Lessons for other jurisdictions wanting to establish legal markets for recreational drugs (including cannabis)**

Perhaps the biggest learning from the experiences summarised in section 10.2.1 is that significant time, resources and planning are required to develop a comprehensive regulatory framework for a new recreational drug market, including investment in capacity building and engagement before the market is established (as discussed in Chapters 5 and 6 and in numerous publications on cannabis law reforms, e.g. Canadian Centre for Substance Abuse (2015); Caulkins (2016); Ghosh et al. (2015); Ghosh et al. (2017); Roffman (2016)).

In terms of implementation timeframe, stakeholders in Colorado recommended allowing “longer than one year” before the launch of retail sales (Canadian Centre for Substance Abuse, 2015). In New Zealand, retail sales under the “interim regime” started immediately following passage of the PSA, which meant that no detailed regulatory instruments for managing the regime were in place. The official advice following the abrupt ending of the interim regime was to “keep transitional provisions short, if at all” (Hannah, 2014), illustrating the challenges with managing the “interim PSA market” and developing regulations at the same time. The slowness in developing and releasing regulations for the full PSA regime was criticised (Chapter 6). Similarly, in Uruguay the delays in establishing pharmacy-based retail network for cannabis was subject to considerable critique, including some media referring to the process as a “huge farce” (Martínez, 2016). Accordingly, policymakers in Canada have adopted a more cautious approach to policy development, with significant effort put into planning and stakeholder engagement before the cannabis law reform takes effect and the law is passed (Task Force on Cannabis Legalization and Regulation, 2016a). It is yet to be seen whether this secures “better law” and a more predictable implementation process.

The above comparison confirms that the design and implementation of a new “regulated drug market” requires significant resources, including monetary, staff and organisational assets. Securing a budget to manage and enforce legal markets is essential. In New Zealand, a range of fees and levies have been imposed on the legal high industry, including a product application fee of 175,000 NZD (MOH, 2014c), to cover direct and indirect costs of managing the PSA (s. 90-97 PSA) (PSRA, 2014c). Colorado and Washington, on the other hand, have imposed product taxes to cover some related public expenses, including implementation of prevention campaigns. In terms of staff and organisational assets, requirements may be higher than anticipated. For example, in Uruguay the scarcity of human resources at the IRCCA led to “long delays in answering any questions or requests” (Decorte et al., 2017). Similar problems have been evidenced in New Zealand. For example, interviewed KIs thought that managing the regime and developing regulations for the full PSA at the same time was challenged by resource constraints, including available personnel and their limited experience (Chapter 6). Some reasons for this may be the novelty of drug market regulation, and related lack of experience and limited knowledge about “best practice” in drug market regulation.

The details of regulatory regimes, such as price control provisions, licensing schemes or advertising restrictions, need a considerable amount of planning. As discussed above, there are multiple options to regulate specific elements of regimes and how legal provisions are framed matters. The legal uncertainties may add to implementation delays (for example, by encouraging the industry to challenge laws, regulations and administrative decisions in courts), and even paralyse implementation of laws (as witnessed with the “animal testing ban” provisions under the PSA). Some commentators have suggested that stringent, health-focused regulations can be achieved by “choosing an aggressive regulatory agency” (Caulkins, 2016), for example an agency located within the portfolio of health or social affairs rather than revenue. While this may be true for some jurisdictions, stringent regulations should not be taken for granted based only on the assumed culture of the government agency leading implementation of the reform. For example, in New Zealand, the regulatory agency for the PSA was located in the Ministry of Health.

Finally, the extent of public support for the “regulated market” regime is an important factor to consider. There is some evidence from New Zealand that public support for the regime may have fallen when communities were faced with the reality of shops selling “recreational drugs” in their neighbourhoods (Chapter 6). Evidence from overseas jurisdictions suggests that where the public is actively engaged in the decision-making processes, for example through a citizens

initiated referendum, the new regime may be more stable. While there is scope to further explore relationships between public support, engagement with civil society and the quality of debate in the media, one lesson for other countries is to probe public opinion about the proposed policy change and secure honest debate about drug regulation in the media.

### **10.2.3 Recommendations for the future implementation of the PSA in New Zealand**

This section brings together learnings from the implementation of the PSA to date, and draws on recent academic literature on the implementation of cannabis law reforms in other countries, in order to propose recommendations for the implementation of the PSA in the future.

#### **(1) Revisit the animal testing ban**

At present, the level of proof required for regulatory approval of a recreational product under the PSA is similar to that for a pharmaceutical product. Toxicology and clinical trials conducted in the process of collecting evidence for regulatory approval under the PSA need to cover aspects of the product's safety, such as pharmacology, general toxicity, assessment of pharmacokinetics and potential to cause addiction (PSRA, 2014a). The limited data available on novel NPS compounds and, most importantly the prohibition on animal testing of products (including results from previous animal trials), effectively make it highly unlikely that sufficient risk data on a NPS product can be provided by a product sponsor to gain approval (Chapter 9). Consequently, for the regulatory regime to move forward in the foreseeable future, the PSA provisions on animal testing need to be revisited. As outlined in Chapter 9, this could involve allowing the use of results from existing animal trials in the product application process. This could mean a pharmaceutical product which has previously failed the therapeutic standard may have enough data to be approved under the PSA.

Alternatively, adoption of another product approval regime not based on the regulatory structure for pharmaceuticals could be considered. For example, under the new dietary supplements regime in New Zealand the regulator will publish a list of substances which are allowed to be marketed as dietary supplements, as long as the products comply with imposed restrictions (e.g. dose limits) (New Zealand Parliament, 2015b). Only products which contain a non-listed substance will need to obtain regulatory approval. Under this regime both scientific and traditional use evidence will be accepted. For a similar "recreational products" regime, the regulatory list could cover some herbal NPS, which are already available in New Zealand but cannot currently be marketed as recreational products without regulatory approval under the PSA (Chapter 4). As discussed in Chapter 4, examples may include *kava kava* or *Lion's tail*.

## **(2) Take a cautious approach to establishing a legal market for new recreational psychoactive products**

Given the issues with managing 47 products approved for the interim PSA regime and the potential for significant commercialisation, a cautious approach to opening up a new recreational drug market is recommended. An incremental approach could be taken, e.g. by allowing only one or two approved recreational products in the first year of the new regulated market, and then increasing the number of approved products in subsequent years, subject to product and system monitoring and evaluation. Given that the PSRA is now legally *required* to approve any product which meets the “low risk” threshold, adoption of this “cautious approach” may require legislative changes. For example, the regulator could be given the power to impose limits on the maximum number of product approvals granted in any given year.

Alternatively, this could be achieved by “slowing down” approval process for the second and any subsequent product using legally stipulated time frames. For example, the Draft Product Approval Guidelines allow 300 days for the initial evaluation of a product application. The industry may object to this option and possibly challenge it in courts, and so this is the less preferred strategy.

## **(3) Prioritise approval of potentially “safer” products**

It is recommended that lower potency products with the least harmful mode of administration are prioritised. For example, faced with approval of two products of similar potency where one is ingested and the other smoked, the PSRA should prioritise approval of the product consumed by ingestion. This approach could give the potentially “safer products” some market advantage. Again, given that the PSRA is now *required* to approve any product which meets the “low risk” threshold, this approach may require changes in the legislation. For example, the regulator could be given the power to prioritise approval of “safer” products based on comparison with other product applications.

At present, the “low risk” threshold for approving products remains undefined and determining which products meet the threshold will be “through assessment by the expert committee, taking into account the nature of each product and its mode of administration” (New Zealand Health Committee, 2013). Once product approvals under the full PSA regime are granted, however, the concept of “low risk” will be clarified. It is recommended that a cautious approach is taken as the initial product approval decisions will set the precedent for subsequent product approval applications.

#### **(4) Engage with stakeholders involved in the product safety monitoring system**

Advanced engagement with stakeholders responsible for reporting adverse events from approved products is needed once a product is approved under the full PSA regime, and preferably well before approval (i.e. when the product application is being processed). This would not only improve the availability of information for regulatory decision-making but also allow for better assessment of the health impacts of the “regulated market regime” in the future.

Stakeholders who should be consulted include health professionals (including GPs) and community representative groups. Stakeholders should be informed about their role in the system for monitoring safety of approved product, and allowed time to provide feedback on how to improve the system and disseminate knowledge about the system among their peers. Advanced engagement will require resources and time.

#### **(5) Further improve product safety monitoring system: integrate national ED database**

The existing data collection systems which capture adverse events from “approved products”, i.e. the national database on ED admissions and hospitalisations, could be better utilised and integrated into the monitoring system for approved products. This would require improved consistency of coding and reporting of adverse events under the ICD (International Classification of Diseases) system currently used. For example, according to the Ministry of Health guidelines, ED visits and hospitalisations involving SC should be recorded under non-specific ICD codes T43.8 (“poisoning by other psychotropic drug”) and F19 (“mental and behavioural disorders due to multiple drug use and use of other psychoactive substances” - in cases of acute SC poisoning), but not T40.7 (“poisoning by cannabis (derivatives)”) (MOH, 2014a). KIs interviewed for this thesis questioned the consistency of coding across emergency departments (Chapter 5). Further, the recording of product brand names is by free text descriptors only, if specified at all (Glue et al., 2016), making this information harder to find and so requiring time and resources for searches. The consistency of coding and the ease of processing information about hospitalisations involving “approved products” should be improved. This could be done by adapting the ICD system used in New Zealand for the purposes of the PSA and creating a new coding category specifically for approved products. This would increase the availability of data for regulatory decision-making and the ongoing monitoring of health impacts of the new regime.

#### **(6) Address gaps in PSA regime: impose product tax**

In view of problems with sales tactics and price-cutting experienced during the interim PSA regime and following examples of cannabis law reform in a number of overseas jurisdictions, it is recommended that additional price control mechanisms (e.g. excise tax or minimum pricing) are included in the PSA regime. In the context of cannabis regulation, there has been extensive policy debate about price control options, e.g. what tax rate to apply and what the tax base for these products should be (i.e. weight of a drug sold, value of a drug or a 'unit of intoxication', such as THC) (Caulkins & Kilmer, 2016). There is no consensus as to what method is best, and it may be that due to the diversity of products, choosing the best tax regime for NPS products will be even more difficult than for cannabis regimes. This should not discourage regulators from imposing a price control mechanism, which can be adjusted later if needed. It seems that the most practical approach for the PSA regime would be excise tax on the value (price) of the product. From a regulatory perspective, this would facilitate control of the market, and also provide additional financial resources for managing the regime.

#### **(7) Regulate retail opening hours**

Introducing controls over the opening hours of licensed PSA retailers is recommended. Given that the power to regulate the location of licensed retailers in districts is delegated to local authorities, the ability to regulate opening hours of licensed retailers could also be given to them. Indeed, some local councils have already included limits on opening hours of licensed retailers in their LAPPs (Martin, 2017), despite the PSA provisions for LAPPs only allowing for limits on the *location* of retailers (PSA, s 68). This discrepancy may be challenged by the industry if an approved legal high market returns. To prevent this, an amendment to s 68 of PSA is needed to specify that the limiting of retailer opening hours may be included in LAPPs. Even with such an amendment, challenges could still follow if limits on hours of operation imposed by LAPPs are too restrictive.

An alternative approach would be to set licensed retailers' hours of operation in the PSA. Another option is to follow regulations in the Sale and Supply of Alcohol Act 2012. Under s 43 default maximum national trading hours are specified. These can be modified by Local Alcohol Policies developed by local councils. One benefit of this approach is that all retailers need to comply with restrictions in the legislation, even when the local authority has not produced a LAPP.

#### **(8) Implement education and prevention campaigns; nominate responsible agency**

The implementation of education campaigns about the law, the products and safe use practices is recommended. Education can be used as a tool for engagement with the public. In terms of the effectiveness of education campaigns in preventing and reducing use, the existing evidence for such approaches is limited. For example, educational programmes about alcohol harms appear to have little long-term effect on consumption and drinking-related problems, and are expensive when compared with other interventions (such as price control or outlet zoning) (Babor, Caetano, et al., 2010). There is some evidence of impact in community-based interventions and strategies focusing on families (Babor, Caetano, et al., 2010). Despite this uncertainty, public education alongside price control and other availability control strategies would be worthwhile in contributing to a wider public-health approach in the PSA. It is also particularly important due to the novelty of policy and the products allowed for sale.

Implementation of education campaigns could be funded from revenue obtained from the proposed product tax (see recommendation 6). For, example, in Washington State, Initiative 502 specifies that 15% of tax revenue remaining after the distribution of funds for monitoring and cost-benefit evaluations of the regime is required to be used for the implementation of educational campaigns. Before regulated sales under the full PSA regime commence in New Zealand, the cost of education and prevention could be partly covered by the product and license application fees. To secure effective implementation, public agency and external partners responsible for education should be clearly identified.

**(9) Clearly communicate future policy changes to the public and monitor public opinion and attitudes towards the PSA and “approved products”**

Advanced communication with the public and relevant stakeholders (including medical professionals, community groups and NPS users) is recommended in case of future policy changes and approval of a “recreational product” under the full PSA regime. To this end, a public consultation process could be included as part of the product approval process. Section 11(3) of the PSA defines matters that the Psychoactive Substances Expert Advisory Committee must have regard to in evaluating product applications, including specific toxicological and pharmacological effects of a product and related risks or potential appeal to vulnerable populations. Section 11(3)(g) also allows for consideration of “any other matters”, and this could cover public opinion on the state of the market (e.g. number and quality of products already available).

**(10) Strengthen enforcement of regulatory restrictions on licensed retailers**

Increased engagement with public health officers tasked with monitoring licensed retailers is needed. Enforcement around legal high retail outlets would benefit from stronger links with the systems for policing compliance of alcohol retailers, including wide adoption of strategies like controlled purchase operations to check for R18 compliance.

**(11) Define rules for engagement with industry actors and ensure transparency in government-industry communications**

In view of previous experiences with the alcohol and tobacco industries, and more recent research on the legal high industry's political and advocacy strategies (presented in Chapter 7), rules for engagement and consultation between government officials and the legal high industry should be clearly established. Any engagement with the industry should be transparent, meaning that the scope of consultations and specific industry actors involved need to be clearly documented, with information accessible to the public. The question of whether the legal high industry should be entirely excluded from any policy-making process, following the approach in the Framework Convention on Tobacco Control (art. 5.3), should be considered.

**(12) Clarify boundaries between the PSA regime and other pieces of legislation**

The boundaries between the PSA and other relevant pieces of legislation (e.g. MODA, Medicines Act, Food Act) could be clarified by establishing more specific rules for classification of substances and products and developing a list of substances deemed to fall under the PSA. Legislative changes in regimes other than the PSA may also help clarify the legal status of some products. For example, once the Natural Health and Supplementary Products Bill is passed into law, the requirement to notify any new ingredient used in a dietary supplement to the regulator would mean that marketing and selling products containing NPS as dietary supplements would be more difficult (New Zealand Parliament, 2015b; Wu, 2015).

Some substances currently classified under MODA (such as cannabis or MDMA) could be transferred to the PSA regime and marketed as "low risk" psychoactive products – provided dose, potency and the mode of administration warrant classification as "low risk", and product sponsors are able to support this claim with scientific evidence. In this case, easing the regulatory pathway for reclassification of substances from MODA to PSA could be of benefit.

**(13) Monitor developments on the "approved products" market, including through commissioning independent research**

Independent research monitoring developments in the regulated PSA market, including patterns of use, users' demographics, market size etc. should be implemented (and funded) immediately at the time of a product's approval. The collection of pre-approval baseline data on use of a specific substance might not be possible due to the nature of the NPS phenomenon and design of the PSA regime (i.e. it is currently unknown what substances will be used as ingredients in "psychoactive products" submitted for approval). Consequently, it is essential to secure funding for research from the very first day of the market's establishment.

### **10.3 Research strengths and limitations**

The use of the mixed methods approach in this research, combining qualitative and quantitative methods of data collection and analysis, was driven by the aim of achieving a deep understanding of the PSA and its implementation. I examined existing official documents, legislation, literature and other available data sources on the PSA and its implementation and supplemented findings from this "formative research" by collecting primary data. This included conducting in-depth interviews with key informants and utilising data from a drug use survey. The validity of findings is substantiated by the triangulation of evidence from analysis of key informant interviews with findings from documentary analysis, legal analysis and quantitative study.

In relation to the qualitative part of this PhD, a number of limitations are acknowledged. The challenges with the implementation of the PSA were explored drawing on observations of key informants (KIs) from various backgrounds. The KIs included politicians and civil servants involved in the development and implementation of the PSA, leading legal high industry figures, and health and NGO actors with knowledge about the regime. A range of KIs from different sectors were interviewed in an effort to capture the diversity of views about the PSA and its implementation. Only four of the 42 invitations sent to KIs were refused, five were ignored, and three invited KIs were not available in the interviewing time frame. It is possible that these actors may have provided valuable observations for this study. Overall, however, I am confident that the key actors from the political, regulatory and industry spheres were interviewed.

Most interviewed participants were generally supportive of the regulatory approach in the PSA and hence were open to providing constructive criticism of its implementation. The in-depth interviews commenced 17 months after the interim regime was ended, and this gap allowed time for reflection, which contributed to a frank and open discussion about implementation challenges. Also, the fact that some KIs were no longer involved in the regime (e.g. regulatory

personnel who had moved to another agency or industry actors who had changed sector) encouraged open answers. As with most interviewing and surveying, however, the time delay may have impeded the participants' ability to recall some specific details.

A number of limitations are also acknowledged in terms of the quantitative data collected and analysed in this PhD (Chapter 8). First, the sample of police arrestees used for the analysis of perceptions of health risk and social acceptability of PSA approved "recreational products" would likely differ from wider society in a range of ways. Police arrestees generally have much higher levels of alcohol and drug use than the general population. It is not clear how this greater experience might impact their perceptions of health risk and social acceptability. On the one hand, more experience of substance use may cause them to be more complacent about risk than the wider population. On the other hand, more experience may make their assessments more informed and accurate. Police arrestees may also be less trustful of government authority and regulation.

#### **10.4 Areas for future research**

There are a number of opportunities to extend the scope of this research. This section outlines some possible research directions which I aim to pursue in the near future.

The PhD has focused on regulatory, legal and social challenges experienced in the PSA implementation, but has not investigated in-depth the role of politics in this policy process. The decision to end the interim regime was largely a political one (subject to a pending general election) and there were political issues throughout the implementation which may have been influential, for example the change in Associate Minister of Health between June 2013 and January 2014. An in-depth examination of political influences would require further background research about the MMP political system and the New Zealand political scene and related drivers. Drawing on work initiated in this PhD, this future research could apply Kingdon's three stream policy window model (Kingdon, 2011) to investigate how the NPS problem came onto the political agenda in the first place, and how the U-turn on the policy followed in May 2013.

Chapter 7 explored how the legal high industry viewed and responded to market regulation using face-to-face in-depth interviews with a number of key informants from the industry. This provided valuable insights into how the LHI operates, including relationships between market competitors and business and political advocacy strategies used. Future research could further explore some of the identified issues using different methodologies. For example, once a regulated market is established under the full PSA regime, an in-depth investigation into the

types of promotions advertised in retail stores and online would add to our understanding of how the new industry approaches market competition (for a similar recent study in the field of alcohol, see for example R. Johnston, Stafford, Pierce, and Daube (2016)). This research could adopt the EMCDDA online snapshot methodology (EMCDDA, 2011).

Given the current absence of a regulated market for NPS in New Zealand, a more immediate research aim is to continue monitoring levels of NPS use and changes in the market, including the emergence of new substances. This could include innovative methodologies such as wastewater analysis (e.g. Lai, Wilkins, Thai, & Mueller, 2017), online monitoring (e.g. Bruno et al., 2013) and pill testing (Butterfield, Barratt, Ezard, & Day, 2016). In terms of current PSA application, further legal and policy research could focus on monitoring how the prohibitive provisions of the PSA are enforced in practice, including the numbers of prosecutions for selling unapproved NPS, the scale of offending for possession of NPS for personal use, and legal analysis of how courts and administrative agencies apply the definition of “psychoactive substance” in future cases.

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## Appendices

### Appendix A: Statement of contribution to Doctoral Thesis containing publications



MASSEY UNIVERSITY  
GRADUATE RESEARCH SCHOOL

#### STATEMENT OF CONTRIBUTION TO DOCTORAL THESIS CONTAINING PUBLICATIONS (DRC16 Form)

We, the candidate and the candidate's Principal Supervisor, certify that all co-authors have consented to their work being included in the thesis and they have accepted the candidate's contribution as indicated below in the Statement of Originality.

**Name of Candidate:** Marta Rychert

**Name/Title Principal Supervisor:** Associate Professor Chris Wilkins

1. **Name of Published Research Output and full reference:**

Rychert, M., & Wilkins, C. (2016). What products are considered psychoactive under New Zealand's legal market for new psychoactive substances (NPS, 'legal highs')? Implications for law enforcement and penalties. *Drug Testing and Analysis*, 8(8), 768-778. Doi: 10.1002/dta.1943

**In which Chapter is the Published Work:** Chapter 4

Please indicate either:

- The percentage of the Published Work that was contributed by the candidate: 80% and / or
- Describe the contribution that the candidate has made to the Published Work: Conception of the project, review of literature for the purpose of the paper, collection and analysis of data, preparing first draft of the paper, revising the paper following supervisors' comments, revising the paper following peer review

2. **Name of Published Research Output and full reference:**

Rychert, M., Wilkins, C. & Witten, K. (2017). Issues with monitoring the safety of psychoactive products under a legal regulated market for new psychoactive substances (NPS) ('legal highs') in New Zealand. *Drug and Alcohol Review*. Published online 23 Feb 2017. Doi: 10.1111/dar.12507

**In which Chapter is the Published Work:** Chapter 5

Please indicate either:

- The percentage of the Published Work that was contributed by the candidate: 90% and / or

- Describe the contribution that the candidate has made to the Published Work: Conception and design of the project, review of literature for the purpose of the paper, data collection (recruiting and interviewing key informants), transcribing data, thematic analysis, preparing first draft of the paper, revising the paper following supervisors' comments, revising the paper following peer review

3. **Name of Published Research Output and full reference:**

Rychert, M., Wilkins, C. & Witten, K. (2017). "Lost in translation": issues with the establishment of a legal market for 'low risk' psychoactive products ('legal highs') in New Zealand. *Drugs: Education, Prevention & Policy*. Published online 2 Feb 2017. Doi: 10.1080/09687637.2017.1282422

**In which Chapter is the Published Work:** Chapter 6

Please indicate either:

- The percentage of the Published Work that was contributed by the candidate: 90% and / or
- Describe the contribution that the candidate has made to the Published Work: Conception and design of the project, review of literature for the purpose of the paper, data collection (recruiting and interviewing key informants), transcribing data, thematic analysis, interpretation of results, preparing first draft of the paper, revising the paper following supervisors' comments, revising the paper following peer review

4. **Name of Published Research Output and full reference:**

Rychert, M. & Wilkins, C. (2016). Legal high industry business and lobbying strategies under a legal market for new psychoactive substances (NPS, 'legal highs') in New Zealand. *International Journal of Drug Policy*, 37, 90-97. Doi: <http://dx.doi.org/10.1016/j.drugpo.2016.08.011>

**In which Chapter is the Published Work:** Chapter 7

Please indicate either:

- The percentage of the Published Work that was contributed by the candidate: 90% and / or
- Describe the contribution that the candidate has made to the Published Work: Conception and design of the project, review of literature, data collection (interviewing key informants), transcribing data, analysis and interpretation of research data, preparing first draft of the paper, revising the paper following supervisors' comments, revising the paper following peer review

5. **Name of Published Research Output and full reference:**

Are government-approved "legal highs" perceived to be safer and more socially acceptable than alcohol, tobacco and illegal drugs? Evidence from New Zealand's regulated legal market regime for new psychoactive substances (NPS)? (not published yet)

**In which Chapter is the Published Work:** Chapter 8

Please indicate either:

- The percentage of the Published Work that was contributed by the candidate: 60% and / or
- Describe the contribution that the candidate has made to the Published Work: Project design, planning analysis (together with statistician and primary supervisor), interpretation of research data, drafting the paper (except one paragraph in the analysis section), review of literature, revising the paper following supervisors' feedback

6. **Name of Published Research Output and full reference:**  
 Rychert, M. & Wilkins, C. (2015). The challenge of a ban on animal testing for the development of a regulated legal market for new psychoactive substances (NPS) ('legal highs') in New Zealand: Issues and options for resolution. *International Journal of Drug Policy*, 26(12), 1273-1278. Doi: <http://dx.doi.org/10.1016/j.drugpo.2015.08.006>  
**In which Chapter is the Published Work:** Chapter 9  
 Please indicate either:
- The percentage of the Published Work that was contributed by the candidate: 80% and / or
  - Describe the contribution that the candidate has made to the Published Work: Conception of the project, review of literature for the purpose of the paper, collection and analysis of data, interpretation of results, preparing first draft of the paper, revising the paper following supervisors' comments
7. **Name of Published Research Output and full reference:**  
 Rychert, M. & Wilkins, C. (2015) Did we have the wrong debate about Elixinol™ and medicinal cannabis? [Letter]. *New Zealand Medical Journal*, 128(1521), 69-70.  
**In which Chapter is the Published Work:** Appendix G  
 Please indicate either:
- The percentage of the Published Work that was contributed by the candidate: 90% and / or
  - Describe the contribution that the candidate has made to the Published Work: Conception of the letter, analysis of relevant legislation, research and analysis of regulatory framework, drafting of the letter, revising the letter following supervisors' comments
8. **Name of Published Research Output and full reference:**  
 Rychert, M. & Wilkins, C. (2016). Thirty-one psychoactive plants exempted from New Zealand's Psychoactive Substances Act 2013 [Letter]. *Addiction*, 112(1), 181-182. Doi: 10.1111/add.13526  
**In which Chapter is the Published Work:** Appendix H  
 Please indicate either:
- The percentage of the Published Work that was contributed by the candidate: 95% and / or
  - Describe the contribution that the candidate has made to the Published Work: Conception of the letter, research and analysis of legal issues, drafting and submitting the letter
9. **Name of Published Research Output and full reference:**  
 Rychert, M., & Wilkins, C. (2017), *New Zealand's pre-market approval regime for 'low risk' new psychoactive substances (NPS, 'legal highs') - a regulatory alternative to prohibition*, in: A. Malczewski (Ed.) *Monitoring drugs and drug addiction on local level*. Warsaw, Poland: Information Centre for Drugs and Drug Addiction. (Published in English and Polish)  
**In which Chapter is the Published Work:** Appendix I  
 Please indicate either:
- The percentage of the Published Work that was contributed by the candidate: 60% and / or
  - Describe the contribution that the candidate has made to the Published Work: Conception of the report (structure and contents), literature review, analysis of

literature and policy sources, drafting of the report, revising the report following supervisors' comments

10. **Name of Published Research Output and full reference:**

Rychert, M., & Wilkins, C. (2015). Is the recent ban on animal testing of legal high products a fatal blow to the development of a legal market for 'low-risk' psychoactive products in New Zealand? [Letter] *Addiction*, 110(4), 713-714. Doi: 10.1111/add.12853

**In which Chapter is the Published Work:** Appendix K

Please indicate either:

- The percentage of the Published Work that was contributed by the candidate: 80% and / or
- Describe the contribution that the candidate has made to the Published Work: Conception of the letter, drafting the letter, revising the letter following supervisors' comments

11. **Name of Published Research Output and full reference:**

Wilkins, C., and Rychert, M. (2017) Recent developments with the New Zealand regulated market approach to 'low-risk' psychoactive products. *Addiction*, 112: 34–36. doi: 10.1111/add.13495

**In which Chapter is the Published Work:** Appendix L

Please indicate either:

- The percentage of the Published Work that was contributed by the candidate: 50% and / or
- Describe the contribution that the candidate has made to the Published Work: conception of ideas in the commentary, critically revising the first draft of the commentary

12. **Name of Published Research Output and full reference:**

Wilkins, C., Byrska, B, Van Hou, M, Corazza, O, Roman-Urrestarazu, A. & Rychert, M. (2017) "Exploring novel policy responses to NPS and 'legal highs' in New Zealand, Poland, Republic of Ireland & the United Kingdom". *Novel Psychoactive Substances. Policy, Economics and Drug Regulation*. Ed. Ornella Corazza, Ed. Andres Roman-Urrestarazu. Springer Nature, 2017

**In which Chapter is the Published Work:** Appendix M

Please indicate either:

- The percentage of the Published Work that was contributed by the candidate: 15% and / or
- Describe the contribution that the candidate has made to the Published Work: Drafting of section about legal control on NPS in Poland, critically revising section about policy response to NPS in Poland

Candidate's signature:  22 June 2017

Principal supervisor's signature:  22 June 2017

## Appendix B: Categorisation of NPS compounds referred to in this thesis

NPS drug family	Compounds referred to in this thesis
Synthetic cannabinoids	5F-ADBICA MDMD-CHMICA AB-FUBINACA PB22 AB-005 PB22-5F AM-2201* SGT-24 CL-2201 SGT-42 CP-55,244 nabilone# JWH-018* dronabinol# JWH-200
Synthetic cathinones	mephedrone (i.e. 4-methylmethcathinone, 4-MMC)* MDPV* methydone* 4-MEC (i.e. 4-methylethcathinone) alpha-PVP (i.e. $\alpha$ -pyrrolidinopentiphenone)
Piperazines	BZP* Trifluoromethylphenylpiperazine (TFMPP) mCPP
Phenethylamines	25B-NBOMe* 25C-NBOMe* 25I-NBOMe* PMMA
Plants	Salvia divinorum Piper methysticum khat kratom Lion's tail
Synthetic opioids	acetylfentanyl AH-7921*
Other	Nitrous oxide# 1,3-dimethylamylamine (DMAA) 1,3-dimethylbutylamine (DMBA)

\* - scheduled by the UN; #- recognised medical use

## Appendix C: Interview protocol

Topic	Question	Politicians/policymakers	Civil servants	Local body representatives	Industry actors	Health & drug policy academics	Health professional/provider	Law enforcement	Community action and NGO
Role in the policy development/implementation and the general attitude	1. Can you tell me about how and when you first became aware/involved in the issue of NPS in NZ? And what is the role of your organisation in the NPS policy/control?	X	X	X	X	X	X	X	X
	2. What is your overall opinion about <i>the idea</i> to regulate legal market for “low risk” psychoactive products as attempted by the NZ policymakers?	X	X	X	X	X	X	X	X
	3. Why do you think it was NZ that forged an innovative approach which was never before tried in any other country, i.e. regulation of the NPS market?	X	X	X	X	X	X	X	X
Process leading up to the PSA	Now I would like to ask you a couple of questions about the process leading up to passage of the PSA.	X	X	X	X	X	X	X	X
	4. First, what is your opinion about the public consultation process? Do you think the public / your organisation was given enough opportunity to participate in the development of the regime?								
Interim regime - challenges	5. Do you think that postulates of your organisations are heard and reflected in the regulatory framework? What are the reasons for this opinion?			X	X	X	X	X	X
	I'm now going to ask you a few questions about the interim regulated legal market and your experiences with it.	X	X	X	X	X	X	X	X
	6. Firstly, how do you evaluate the decision to establish the interim market?								
	7. From your point of view, what were its advantages?	X	X	X	X	X	X	X	X

Topic	Question	Politicians/policymakers	Civil servants	Local body representatives	Industry actors	Health & drug policy academics	Health professional/provider	Law enforcement	Community action and NGO
	<p>Now moving on to the criteria for temporary approval of products.</p> <p>8. What did you think of these? (if not familiar, explain)</p> <p>9. What did you think of the resulting number of products (i.e. down from estimated 200-300 products to 45)?</p> <p>10. And what did you think about the price of interim approved products?</p> <p>11. Have you noticed any changes in product prices?</p> <p>12. And how did you view the retail outlets restrictions during the interim regime?</p> <p>13. And what did you think about the resulting number of outlets? (down from 3,000-4,000 down to 150 outlets)?</p> <p>14. What were the main challenges faced by your organisation/profession during this period?</p> <ul style="list-style-type: none"> <li>- In your view, what was the impact of the interim regime on <b>health services</b>? What are the reasons for this assessment? Have additional resources been allocated to health services during the interim regime?</li> <li>- Do you know how <b>monitoring of adverse health effects</b> from interim approved products was carried out? How were adverse events reported, where was information collected? How well do you think the system worked?</li> <li>- What were the main challenges faced by the <b>law enforcement</b>? Have additional resources been allocated? How do you evaluate the burden on law enforcement? How do you evaluate the impact of the interim regime on the black market for drugs and NPS?</li> <li>- Are you satisfied with how the criticism of creating legal market was dealt with on a <b>political</b> level? How did you view public communication around the policy?</li> </ul>	X	X	X	X	X	X	X	X

Topic	Question	Politicians/policymakers	Civil servants	Local body representatives	Industry actors	Health & drug policy academics	Health professional/provider	Law enforcement	Community action and NGO
	- How did you view <b>competition</b> on the market? What were the strategies used in your company to stand this competition? How did other businesses respond?				X				
	- If you could revisit your actions, what would you have done differently?	X	X	X	X	X	X	X	X
	15. What's your opinion about the decision to end the interim regime in May 2014? Why?	X	X	X	X	X	X	X	X
Animal testing	In May 2014 the ban on animal testing was introduced.								
	16. What is your opinion about this decision?								
	a. Where do you think the pressure came from?	X	X		X	X			X
	b. Why do you think the initial consensus (animal testing only if no alternative) proved insufficient at a later stage?	X							
PSA legislation	Now I would like to move to the actual content of the law and regulations; i.e. the intended way the regime would work and the principles underpinning the regime.	X	X	X	X	X	X	X	X
	17. How do you see the role of harm reduction under the PSA regime?	X	X		X	X	X	X	X
	18. The decision was made to not specify elements of 'low-risk' definition in the legislation or regulations to allow some flexibility? What do think about that decision?	X	X		X	X			
	19. The new regulations align products safety requirements with standards for medicines, which means that the industry needs to provide evidence from advanced toxicity tests, including pre-clinical and clinical trials. What do you think of this?	X	X		X	X	X		X
	20. How do you evaluate the standards set in the Code of Manufacturing Practices?								
	21. How do you see the regulatory burden on the industry?	X	X		X				
	- What is the reason for this opinion?	X	X		X				X

Topic	Question	Politicians/policymakers	Civil servants	Local body representatives	Industry actors	Health & drug policy academics	Health professional/provider	Law enforcement	Community action and NGO
	22. Framework for the retail regime for NPS has been broadly aligned with similar alcohol and tobacco regulations. This includes licensing of retailers (like for alcohol) and R18 purchase. What do you think about these standards for NPS? What do you think are the strengths of this approach? What are the weaknesses?	X	X	X	X	X	X	X	X
	23. Local communities have been given powers to implement LAPP which may limit location of retail outlets. What's your opinion about this? Do you think they should be allowed to impose a total ban on sale of NPS in their communities?			X					X
	24. What's your opinion about not introducing excise tax until market has been established and going?	X	X		X				X
	25. During development of the regime there was discussion as to whether possession of not-approved NPS should be punished. The decision was made to sanction possession for personal use with an administrative fine. What's your opinion about this?	X				X	X	X	X
	26. Do you think that this measure is achieving its objective of "directing youth to health providers", as intended by the policymakers?						X	X	
	27. If you could redesign the law, what would you change?	X	X	X	X	X	X	X	X
Overall assessment and future expectations	Now, reflecting on the current situation.	X	X	X	X	X	X	X	X
	21. How do you see the progress with the implementation to date? Why?								
	22. Do you think the PSA is achieving its objective? To what extent you think it "solves the NPS problem" in NZ?	X	X	X	X	X	X	X	X
	23. Given the experience with implementation of the PSA, how do you <u>now</u> see the idea to establish regulated market for NPS?	X	X	X	X	X	X	X	X
	24. How do you see the future of the regime? Who do you think should play major role in the future establishment of the market?	X	X	X	X	X	X	X	X

## Appendix D: Participant information sheet

### Implementation of the *Psychoactive Substances Act* 2013 - stakeholders' perspectives



#### INVITATION TO PARTICIPATE IN A RESEARCH STUDY (PROJECT INFORMATION)

My name is Marta Rychert and I am a PhD candidate at Massey University. This research project is a part of my PhD dissertation which aims to study innovative policy responses to new psychoactive substances (NPS) in New Zealand and around the world. I am originally from Poland and have previously analysed approaches to NPS in Europe while working at the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in Lisbon. My PhD supervisors are Dr Chris Wilkins and Professor Karen Witten from SHORE & Whariki Research Centre, College of Health, Massey University.

This study focuses on New Zealand's world leading response to NPS, the Psychoactive Substances Act (PSA), and the process of its implementation. I am aiming to better understand the development of the PSA and its implementation process by interviewing stakeholders from various backgrounds, including health providers, private industry, research centres, law enforcement, community groups, regulatory bodies and policymakers.

You are invited to take part in this research. Your participation will involve an interview focusing on the successes and challenges at different stages of the policy process. The estimated time of an interview is 40 minutes and I would prefer to conduct it face-to-face. The interview will be confidential and your name or affiliation will not be disclosed. Your interview will only be identified as a generic stakeholder type (e.g. health provider, private industry).

#### What will happen with the data

Findings of the project will be published in a peer-reviewed academic publication and will be included in my PhD dissertation.

Interviews will be recorded and transcribed to assure accuracy of information. Data will be available to me and to my PhD supervisors only, and not disclosed to any third parties. Transcripts and recordings will be stored securely in electronic form for a period of two years and then disposed of.

#### Your rights

You are under no obligation to accept this invitation. If you decide to participate, you have the right to:

- decline to answer any particular question;
- withdraw from the study up to two weeks after completion of the interview;
- ask any questions about the study at any time during participation;
- provide information on the understanding that your name and affiliation will not be used unless you give express permission to the researcher;
- be only referred to in the results as a generic stakeholder category (e.g. health provider, private industry);
- be given access to a summary of the project findings when it is concluded;
- ask for the recorder to be turned off at any time during the interview.

Please contact me or my supervisor if you have any questions about the project.

**Researcher:**  
Marta Rychert  
m.rychert@massey.ac.nz  
Mob: 021 423 697

**Supervisor:**  
Dr Chris Wilkins  
c.wilkins@massey.ac.nz

This project has been evaluated by peer review and judged to be low risk. Consequently, it has not been reviewed by one of the University's Human Ethics Committees. The researchers named above are responsible for the ethical conduct of this research.

If you have any concerns about the conduct of this research that you wish to raise with someone other than the researcher(s), please contact Dr Brian Finch, Director, Research Ethics, telephone 06 356 9099 x 86015, email [humanethics@massey.ac.nz](mailto:humanethics@massey.ac.nz).

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Email: [shore@massey.ac.nz](mailto:shore@massey.ac.nz) Web: [www.shore.ac.nz](http://www.shore.ac.nz)



## Appendix E: Participant consent form



### *Implementation of the Psychoactive Substances Act – stakeholders' perspectives*

#### PARTICIPANT CONSENT FORM

I have read the Information Sheet and have had the details of the study explained to me. My questions have been answered to my satisfaction, and I understand that I may ask further questions at any time.

I agree/do not agree to the interview being sound recorded.

I wish/do not wish to have my recordings returned to me.

I agree to participate in this study under the conditions set out in the Information Sheet.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Full Name - printed \_\_\_\_\_

## Appendix F: Transcript release authority form



### *Implementation of the Psychoactive Substances Act 2013 – stakeholders' perspectives*

#### **AUTHORITY FOR THE RELEASE OF TRANSCRIPTS**

I confirm that I have had the opportunity to read and amend the transcript of the interview(s) conducted with me.

I agree that the edited transcript and extracts from this may be used in reports and publications arising from the research.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Full Name - printed \_\_\_\_\_

## Appendix G: Letter published in the *NZMJ*: Did we have the wrong debate about Elixinol™ and medicinal cannabis?

Rychert, M. & Wilkins, C. (2015) Did we have the wrong debate about Elixinol™ and medicinal cannabis? [Letter]. *New Zealand Medical Journal*, 128(1521), 69-70.

The recent approval of a cannabis-derived product Elixinol™ for the treatment of a coma patient suffering from *status epilepticus* has renewed the public debate on medicinal cannabis reform in New Zealand.<sup>1</sup> The Associate Minister of Health, Peter Dunne, approved the one-off use of Elixinol™ “on compassionate grounds”, despite the lack of clinical evidence about the efficacy of the product for the treatment of this particular condition.<sup>2</sup> The public and media debate which followed ignored the fact that Elixinol™ is not a medicine or a pharmaceutical-grade cannabis product.

Elixinol™ is actually marketed and sold as a dietary supplement, with claimed benefits limited to the antioxidant properties of cannabidiol (CBD).<sup>3</sup> It is 18% CBD oil extract produced from pressing stalks and seeds of industrial hemp,<sup>3</sup> i.e. a variety of *cannabis sativa* plant with low tetrahydrocannabinol (THC) content (generally below 0.3%).<sup>4</sup> Although there is a growing evidence base supporting the therapeutic benefits of CBD,<sup>5</sup> the US manufacturer of Elixinol™ does not make any therapeutic claims. The product is non-psychoactive as it does not contain any THC, the psychoactive constituent of *cannabis sativa*. Despite being a non-psychoactive and non-medicinal product, in New Zealand Elixinol™ falls either under the *Misuse of Drugs Act 1975* (MODA) which prohibits the use, possession and supply of cannabis preparations, or under the medicines regime if granted ministerial approval for therapeutic use on case-by-case basis (as in the recent case).

Cultivation of industrial hemp is licensed in New Zealand<sup>6</sup> and there are a number of hemp-derived products available on the market.<sup>7</sup> For example, hemp soap is regulated as a cosmetic product, hemp seed oil (a non-psychoactive oil pressed from industrial hemp seeds) is regulated as a food product, hemp protein powder and whole hemp seeds are allowed for sale in animal fodder.<sup>7</sup> These examples show that the default classification of *cannabis sativa* under the MODA does not preclude regulation of non-psychoactive hemp products under alternative legal regimes, as long as the products comply with the requirements of these regimes, including product safety standards. Non-psychoactive CBD oil extracts, such as Elixinol™, could be regulated in a similar way, resulting in wider access to these products. According to the MedSafe categorisation of products guidelines<sup>8</sup> the CBD oil extracts appear to fit under the legal regime for dietary supplements.

The issue of products with broadly the same ingredients being regulated under different regulatory regimes with implications for legal status has assumed greater importance since the enactment of the *Psychoactive Substances Act 2013* (PSA). For example, kava (*Piper methysticum*), a plant traditionally used in Pacific cultures, can be legally sold when it falls under the Food Act (traditional representation as a drink) and the Dietary Supplement Regulations (pills marketed for their nutritional value),<sup>9</sup> but is currently prohibited as an ingredient in ‘legal highs’, i.e. when it is represented as a recreational drug under the PSA.<sup>10</sup> In such a complex regulatory environment, there needs to be greater transparency about how products are classified and more clarity about the legal status of different products.

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## Appendix H: Letter published in *Addiction*: Thirty-one psychoactive plants exempted from New Zealand's Psychoactive Substances Act 2013

Rychert, M. & Wilkins, C. (2016). Thirty-one psychoactive plants exempted from New Zealand's Psychoactive Substances Act 2013 [Letter]. *Addiction*, 112(1), 181-182. Doi: 10.1111/add.13526

Following passage of the UK *Psychoactive Substances Act* 2016 (UK PSA) there has been extensive debate around legal definitions of “psychoactivity”. Ireland (2010), Poland (2010), Romania (2011), New Zealand (2013), Australia (2014), and the UK (2016) have all passed laws where new psychoactive substances are broadly defined by their capability to influence the user’s mind, mood, brain or behaviour. In the UK, the new definition has been criticised for being “extraordinarily broad” [1] and “conceptually fraught” [2].

Three years after the passage of New Zealand’s *Psychoactive Substances Act* 2013 (NZ PSA) controversy about what products are deemed psychoactive and hence covered by the Act has persisted. Most recently, in April 2016, the Psychoactive Substances Regulatory Authority (PSRA), the government agency overseeing implementation of the NZ PSA, published a list of 31 plant species which they consider are not covered under the NZ PSA, at least as they note “at this time” [3]. The list includes plant species such as Yerba Mate, Passionflower and Wormwood. The list was compiled based on the PSRA’s understanding that it is not the intent of the NZ PSA to capture these plants as they produce “only low level of psychoactive effects and have been available in New Zealand and internationally for decades with no evidence of adverse reactions” [3]. However, the legal definition of “psychoactive substance” in the NZ PSA doesn’t specify any minimum extent of psychoactive effect or any minimum level of harmfulness needed for a substance to be covered by the legislation [4].

The criteria used to select the 31 exempted plant species is not made explicit by the PSRA but there is reason to believe it has not been consistently applied. For example, the list doesn’t contain Ginkgo Biloba, a tree commercially grown in New Zealand, whose leaf extract has been reported to produce mild enhancement of cognitive function [5]. Piper methysticum (kava kava), a psychoactive plant popular among Pacific communities due to their traditional ceremonial use of drink made from kava roots [6, 7], is also not on the list. Both plants are legally marketed as ingredients in products exempted from the NZ PSA regime, such as food, dietary supplements or herbal remedies [8]. However, when marketed as “recreational products” they should fall under the NZ PSA [4]. For example, a number of recreational psychoactive products containing kava are currently listed as “unapproved psychoactive products” [9].

The list of plant species exempted from the NZ PSA is a good start to clarify the legal status of some plants, but greater transparency and consistency in making these classification decisions is desirable. Also, the legal basis for these regulatory exemptions is unclear (as under the NZ PSA it is the Governor General who has the legal power to declare substances or products to be or not to be “psychoactive substances”, s.99 PSA) which means the new list remains an opinion only and does not necessarily result in greater legal certainty for businesses involved in trade of psychoactive plants.

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## Appendix I: Publication for the Polish Drug Information Centre: New Zealand's pre-market approval regime for 'low risk' new psychoactive substances (NPS, 'legal highs') - a regulatory alternative to prohibition

Rychert, M., & Wilkins, C. (2017), *New Zealand's pre-market approval regime for 'low risk' new psychoactive substances (NPS, 'legal highs') - a regulatory alternative to prohibition*, in: A. Malczewski (Ed.) *Monitoring drugs and drug addiction on local level*. Warsaw, Poland: Information Centre for Drugs and Drug Addiction. (Published in English and Polish, title of article in Polish: *Regulowany rynek nowych substancji psychoaktywnych (NSP, "dopalaczy") w Nowej Zelandii: alternatywa dla delegalizacji*)

### 1. Introduction

The rapid emergence of a range of new psychoactive substances (NPS), which are often marketed as 'legal' alternatives to prohibited drugs (hence internationally called 'legal highs'), has challenged the United Nations international drug control system and national drug control frameworks (Brandt, King, & Evans-Brown, 2014). With over 560 NPS compounds currently being monitored by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), of which more than 70% have been detected in the last five years (EMCDDA & Europol, 2016), there are no signs of a slowdown in the global NPS phenomenon.

Overwhelmingly, the response to the influx of NPS has been to prohibit the sale of these compounds, either by adding them to the lists of prohibited substances in national drug laws or by imposing bans on broad categories of substances defined by their similarity to already scheduled drugs (generic and analogue approaches). In a more recent development, a number of countries, including Poland, have imposed so-called 'blanket bans' which prohibit the sale of any psychoactive product. These prohibitive approaches have been criticised for a number of reasons, including practical challenges with policing (Malczewski, 2015), the increasing administrative burden for academic researchers (Kavanagh & Power, 2014) or driving NPS users underground (Stevens, Fortson, Measham, & Sumnall, 2015).

New Zealand adopted a regulatory approach to NPS, which sits in stark contrast to prohibitive measures implemented in other countries (Wilkins et al., 2013). In July 2013, the New Zealand Parliament passed the *Psychoactive Substances Act (PSA)*, under which developers of NPS products are allowed to legally manufacture and sell their products in a controlled regulated environment if they prove that their products are "low risk" (with associated expenses to prove products are "low risk" met by their sponsors) (New Zealand Parliament, 2013a). This novel approach to NPS received considerable international attention as a possible solution to the ongoing problems with NPS that could be adopted in other countries (Seddon, 2014; UK NPS Review Expert Panel, 2014).

### 2. Recreational drug market and the emergence of NPS in New Zealand

New Zealand, an island nation in the South Pacific populated by 4.5 million people, is separated from its nearest neighbour Australia by some 2,000 km of Tasman Sea. Its geographical isolation has had a long influence on traditional illegal drug markets, with drugs that need to be smuggled from other countries, such as cocaine and heroin, of uncertain supply and limited use (Wilkins, Prasad, Wong, & Rychert, 2015). Locally produced drugs, primarily cannabis and

methamphetamine, have traditionally been more available. As in most Western countries, cannabis has been the most widely used illegal drug for many decades now, with the latest general population survey reporting 14% of adult population (defined 15-64) used cannabis in the last year (MOH, 2015). The situation with methamphetamine is distinctive, with prevalence rates high by international standards (1.1% last year use in general population (MOH, 2014a)) and a domestic production chain. The relative absence of alternative drugs for many years and their high prices by international standards created demand for alternative synthetic stimulants and hallucinogens, elsewhere satisfied by illicit supply of MDMA.

Around 2000, New Zealand entrepreneur Matt Bowden developed a range of products containing the synthetic stimulants benzylpiperazine (BZP) and trifluoromethylphenylpiperazine (TFMPP) (Wilkins & Sweetsur, 2010). Bowden, previously addicted to methamphetamine, presented his product as a lower risk, safer alternative to methamphetamine (Kerr & Davis, 2011). His company *Stargate International* marketed BZP ‘party pills’ on a commercial scale, with much of the manufacturing happening in India and China, thanks to then unregulated status of BZP internationally (Szalavitz, 2015). BZP soon grew in popularity among wider groups of users as a new recreational ‘legal high’ product and it is estimated that by 2004 approximately five million legal BZP/TFMPP party pills had been sold on the unregulated market, amounting to sales of 24 million New Zealand Dollars (NZD) per year (15 million EUR = 67 million PLN) (Wilkins & Sweetsur, 2010). The growing popularity of BZP and uncertainties around potential health impacts created the need for a response from the government.

### 3. First regulatory attempt under the Misuse of Drugs Act

In line with the evidence-based drug policy making, the New Zealand government commissioned an evaluation of BZP safety. In 2004, the Expert Advisory Committee on Drugs (EACD) concluded that existing evidence on BZP-related health harms was insufficient to make an informed scheduling decision (EACD, 2004). While the EACD commissioned further research, they recommended that some form of government regulation was required to control the existing BZP market.

In 2005, a new regime for substances assessed by the government to be “low risk” was established by amendment of the Misuse of Drugs Act (MODA), and the BZP was immediately included in the new schedule (New Zealand Parliament, 2005). The so-called “Restricted Substances Regime” (RSR) imposed broad market regulations, such as an age limit on sale (i.e. 18 years or older), limited advertising and no giving away of free product samples (Sheridan & Butler, 2010). The legal high industry continued commercial sales of their products under this limited regulatory regime. It is estimated that in 2007/2008, at the height of BZP party pill popularity, they were selling 200,000 party pills per month, with a product range of around 80 to 120 brands (Wilkins et al., 2013). More detailed government regulation of the RSR, including product quality standards and maximum dose limits, was anticipated. However, their introduction in late 2008 didn’t impact on the BZP market as it had been brought to an end before these restrictions took effect. In 2008, based on new evidence of BZP-related health harms, including from previously commissioned government research (e.g. Thompson et al., 2006), BZP was scheduled as a Class C drug under MODA and thus became a prohibited substance.

Despite the RSR regulatory regime being active legislation until 2013, regulatory provisions remained dormant as no other substance apart from BZP was ever controlled under this regime. However, the three years of experience with regulating BZP between 2005 and 2008 provided the grounds for the upcoming regulations for NPS.

#### 4. Towards the new pre-market regulatory approval regime

The “legal highs” industry responded to the ban on BZP by shifting production to non-BZP party pills and synthetic cannabinoids, which were not controlled by any legislation (Wilkins et al., 2013). Synthetic cannabinoids became increasingly popular after 2010 and, similarly to BZP products, were sold from convenience stores without any regulatory restrictions. Again, little was known about their health impacts and the speed of government response was limited due to the slowness of assessment and scheduling processes.

Between 2011 and 2013 a number of products were taken off the market by means of a new legislative measure (the so-called Temporary Class Drug Notices), which allowed the New Zealand Ministry of Health (MOH) to ban specific substances for a maximum period of two years pending their risk-evaluation. The temporary bans covered 33 compounds, including JWH-018 and JWH-073 sold as ingredients in the Spice and Kronik brands (MOH, 2011). Despite the bans, Ministry of Health (MOH) estimated that approximately 200–300 psychoactive products were being sold from around 3,000–4,000 retail outlets in 2013 (MOH, 2014b).

The ongoing problems with NPS came to attention of the New Zealand Law Commission (NZLC), an independent expert body which reviews New Zealand laws and makes recommendations for improvements to the government. In 2011, as part of its review of the Misuse of Drugs Act, the Law Commission concluded that the government could not keep up with the market by banning individual compounds, as producers easily circumvent new controls by instantly substituting newly scheduled drugs with new uncontrolled compounds. The NZLC recommended the development of a new pre-market approval regulatory regime requiring producers of NPS products to demonstrate their products are safe *before* they are permitted to be sold on the legal market (rather than the government having to prove that the products are unsafe in order to remove products from the market). Forty-five recommendations on how the new pre-market approval regime should operate were included in the final NZLC report, including restrictions on retail sale and advertising (NZLC, 2011). The NZLC report became a guiding document for further work on the new legal high regime, including the Ministry of Health Regulatory Impact reports, where details of regulatory options were discussed.

#### 5. Psychoactive Substances Act: key concepts and legislative mechanisms

The *Psychoactive Substances Act* (PSA), which established the world’s first pre-market approval legal regime for NPS was passed in July 2013 with nearly unanimous cross-party support in Parliament (119 in favour and 1 vote against the legislation) (New Zealand Parliament, 2013b). Under this regime, developers of NPS products can receive government approval to legally manufacture, import and sell their products, provided they can prove through pre-clinical and clinical trials that their products cause no more than a “low risk” of harm to an individual using them (Wilkins, 2014a). The importation, manufacture, supply and possession of any other ‘unapproved’ NPS is prohibited by default (Rychert & Wilkins, 2016).

Requirements for testing the safety of psychoactive products resemble the pre-market approval regime for medicines and are modelled on pharmaceuticals standards developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This means that scientific evidence from a series of toxicology and clinical trials is required for each product application, and this should cover aspects of the product’s safety such as pharmacology, general toxicity, assessment of pharmacokinetics, metabolism and potential to cause addiction (PSRA, 2014). The approval is granted for each separate *product formulation* (not *substance*), and thus the strength of the product cannot be modified once

approval is granted. The New Zealand Ministry of Health have estimated that the cost of testing is likely to be 1–2 million NZD (2.8 mln – 5.5 mln PLN) per product (MOH, 2013). The product application fee is set at 175,000 NZD per product. While this might seem like a lot of money, returns from the market are likely to compensate the initial expenses. The estimated annual retail sale from a regulated synthetic cannabis market during the “interim phase” of the PSA’s implementation reached 140 million NZD (385 mln PLN) (MOH, 2014b).

The retail framework for the regime is modelled on regulations for alcohol and tobacco, with approved products allowed to be legally sold only from specialised licensed retail outlets. No food or alcohol can be sold from the same premises and the PSA explicitly bans sale of products from supermarkets, petrol stations, local convenience stores or alcohol retail outlets. Retail sales are only allowed to customers 18 years of age and over (which matches the legal drinking age limit in New Zealand). Further restrictions on location of licensed retailers, including minimum distance from “sensitive sites” such as schools, sports fields or churches can be imposed by local councils, but local communities are not allowed to impose a total ban on the sale of approved products in their districts. Around half of the 71 local authorities in New Zealand have adopted these extra policies (PSRA, 2015), with most of them limiting the location of retail outlets to city centres and out of residential suburbs.

The advertising of approved NPS products is limited to the ‘point-of-sale’ only (i.e. no advertising in television, radio, or newspapers) and must be limited to objective information about the product, such as active ingredients and the price. The PSA specifically prohibits advertising in a form which conveys a message that an approved product is ‘safe’. While online sale of products is allowed, it can only be done through websites established specifically for this purpose (but not other internet platforms, including social media websites). Packaging for NPS products must include a list of ingredients, health warnings, contact details of the manufacturer and the telephone number of the National Poisons Centre (New Zealand Parliament, 2013a).

The Psychoactive Substances Regulatory Authority (PSRA), a new government agency established within the Ministry of Health, was tasked with overseeing implementation of the PSA. The PSRA has the ability to revoke any product approval if, after introducing the product to the market, reports about adverse effects emerge and the product is no longer considered to be “low risk”.

#### 6. Challenges in implementation of the PSA during the “interim regime”

When the PSA was passed in July 2013, much of the regulatory framework required for the regime to become fully operational had yet to be completed, including the required safety testing standards. While these regulations were being developed by the PSRA, the “interim regime” was established, which allowed a limited number of products available on the market before passage of the PSA to continue to be sold subject to new retail and advertising restrictions under the PSA. Forty-seven products received interim approvals, forty of which were synthetic cannabinoid smoking blends containing compounds such as AB-FUBINACA, PB-22, CL-2201, or SGT-24 (Wilkins, 2014b). These product did not pass any safety tests but were „deemed to be low risk“ as they had been on the market for at least three months before the PSA and there were no adverse effect notifications against them. One-hundred and fifty-two specialised retailers were licensed to sell the “interim approved“ products.

Managing the market during the interim stage of PSA implementation proved challenging. The choice of products allowed to stay on the market during the interim regime was questioned, with ongoing reports about harms and social disruption around retail outlets. The system for monitoring product safety was not fully developed at the time the interim regulated market was

established and hence the process of removing products which caused harm lacked speed and efficiency. New retail restrictions, which reduced the number of retail outlets from around 3–4,000 pre-PSA to 152 specialised shops, resulted in the unintended consequence of concentrating demand in a limited number of shops, which increased visibility of shops and focused negative media attention. All these factors, in combination with pressure on politicians created by the impending general election scheduled for September 2014, resulted in withdrawal of all interim product approvals and interim retail licenses by an amendment to the PSA in May 2014.

The May amendment came with another significant change to the PSA testing regime, i.e. a prohibition on the use of animal tests to demonstrate that products are “low risk”. The animal testing ban followed public protests against the harming of animals for the purpose of testing products with no therapeutic effect (Rychert & Wilkins, 2015b). The PSRA has gone so far as to state that ‘it is unlikely that a product can be shown to pose no more than a low risk of harm without the use of animal testing’; suggesting the PSA was now unworkable (PSRA, 2014). A strategic analysis of the situation suggests there are a number of options to ‘work around’ the animal test ban, but the two most viable would require some political support and the tacit acquiescence of the regulator (Rychert & Wilkins, 2015a). Without these, the regime may be stalled until non-animal models for testing psychoactive products safety are developed and recognised internationally.

#### 7. Future of the PSA and concluding remarks

Since the ending of the “interim regime”, the PSA product approval framework has been finalised, and in November 2014 the regime was opened to receive product applications under the full “low risk” testing framework. As of July 2016, there are no approved products on the market and no product applications under regulatory consideration. Given that no “low risk” psychoactive product has ever been approved and marketed under the full PSA regime, the benefits and unintended consequences of the regulatory approach are yet to be seen and evaluated. The challenges experienced during the “interim phase” of PSA implementation offer a number of learnings for the future implementation of the PSA in New Zealand and for other jurisdictions that might be interested in adopting a similar regulatory approach. Perhaps the biggest lesson is that designing a regulatory regime for recreational psychoactive substances will take a lot of time and resources to plan and design implementation of key systems and for ongoing engagement with stakeholders (including local communities and the media).

The experiment with regulating NPS under the PSA was facilitated by a number of social and geo-political factors specific to the New Zealand context, including its geographical isolation, the early appearance of politically-skilled and economically powerful industry players, the previous regulatory experience with BZP, and a favourable political environment. The question of whether regulatory solutions in the PSA could be successfully implemented elsewhere, including Poland, remains open. The 2014 report of the UK Panel of Experts reviewing policy options to address NPS issues in the UK, praised the New Zealand approach as “bold and innovative” with a potential to reduce overall NPS-related harms, and called on the UK government to monitor the developments in New Zealand as a potential model to follow in the future (UK NPS Review Expert Panel, 2014). While the UK government adopted a “blanket ban” legislation which prohibits manufacturing and supply of any substance with psychoactive effects, calls to review alternative regulatory options and implement more measured approaches, such as the regime proposed in the New Zealand’s PSA, continue (Feilding & Singleton, 2016; Reuter & Pardo, 2016).

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## Appendix J: Univariate analysis results (preliminary analysis for Chapter 8)

For the purpose of preliminary analysis for Chapter 8, univariate analysis of health perceptions and social acceptability scores was completed. For this exercise data from both 2014 and 2015 NZ-ADUM waves was used. This initial statistical analysis gave me insight into the data and informed the subsequent multivariate model as presented in Chapter 8. It was subsequently decided to drop the 2015 data to reduce the number of comparisons and because these interviews were conducted after the ending of the interim regime.

In the preliminary analysis, the mean scores for perceptions of health risk and social acceptability of the drugs were compared between all drug and sociodemographic groups using ANOVA models. The analysis was done separately for each category of user group and year. P-values were adjusted for multiple comparisons via the Tukey-Kramer method. Paired t-tests were used to detect differences in an individual's scores for approved and unapproved synthetic cannabis/party pills. All analyses were performed in SAS (9.3) and results were deemed significant at  $\alpha=0.05$  (for comparison of mean scores using ANOVA models), and at  $\alpha=0.01$  (for comparison of paired t-test individual scores because of the large number of tests being performed).

### Most positively rated drugs

Table 1 presents mean scores of the health risks and social acceptability for all drugs types for both 2014 and 2015 as rated by the total sample, by different drug users and by sociodemographic groups. Overall, natural cannabis was considered least risky to health (Figure 1), with the difference between the health risk of natural cannabis and all other drugs statistically significant for the total sample and for the sub-samples of regular and occasional SC users. The only exception was the group of "legal drug users only" who considered alcohol the safest. Overall, alcohol was considered the most "socially acceptable" drug, with the difference in the social acceptability score for alcohol and all other drugs statistically significant for the total sample (except in 2015, where the difference between alcohol and tobacco was not significant).

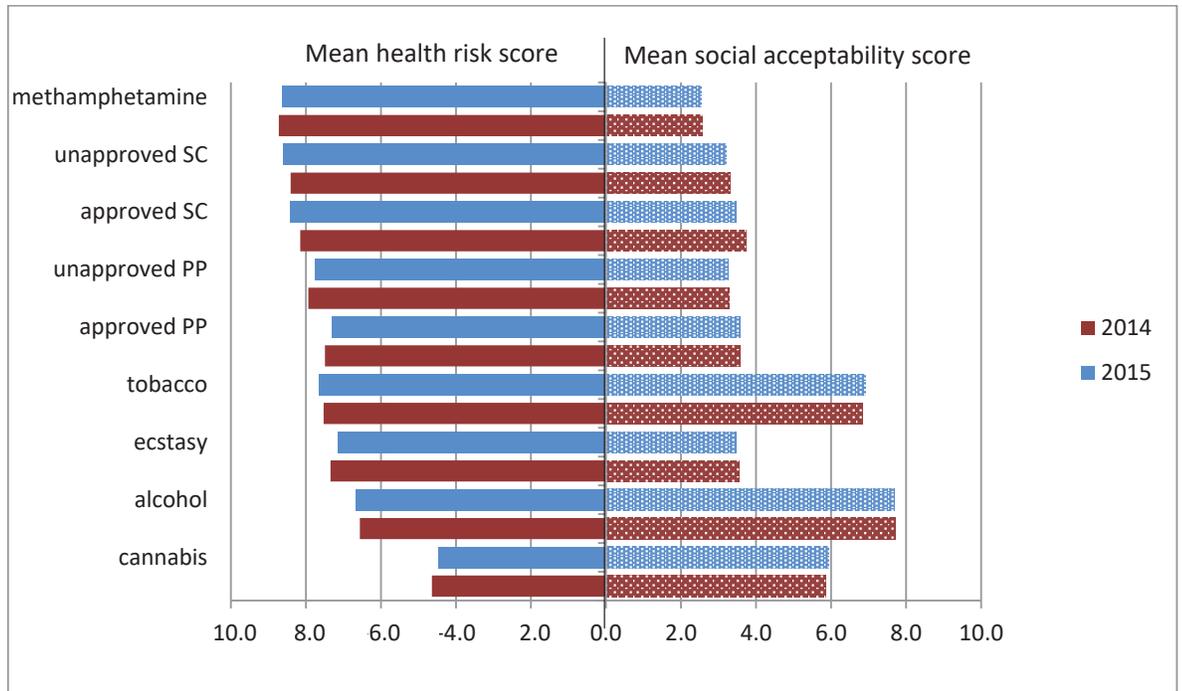


Figure 1: Mean health risk and social acceptability perception scores for all drugs by the whole sample in 2014 and 2015

**Table 1: Mean health and social acceptability scores**

		Health perceptions												Social acceptability																									
		2014						2015						2014						2015																			
N		methamphetamine	Unapproved SC	Approved SC	Unapproved PP	tobacco	Approved PP	ecstasy	alcohol	cannabis	methamphetamine	Unapproved SC	Approved SC	Unapproved PP	tobacco	Approved PP	ecstasy	alcohol	cannabis	methamphetamine	Unapproved SC	Approved SC	Unapproved PP	tobacco	Approved PP	ecstasy	alcohol	cannabis											
	2014	834	8.7	8.4	8.1	7.9	7.5	7.3	6.6	4.6	8.6	8.6	8.4	7.8	7.6	7.3	7.1	6.7	4.5	2.6	3.3	3.7	3.3	6.8	3.6	7.7	5.9	2.5	3.2	3.5	3.3	6.9	3.6	3.5	7.7	5.9			
	2015	835	8.7	8.4	8.1	7.9	7.5	7.3	6.6	4.6	8.6	8.6	8.4	7.8	7.6	7.3	7.1	6.7	4.5	2.6	3.3	3.7	3.3	6.8	3.6	7.7	5.9	2.5	3.2	3.5	3.3	6.9	3.6	3.5	7.7	5.9			
Total sample																																							
SC users:																																							
	2014	207	8.5	8.0	7.5	7.3	7.1	6.8	6.9	6.4	3.9	8.4	8.4	7.9	7.3	7.3	6.5	6.9	6.6	3.8	2.3	4.2	5.1	3.7	7.5	4.3	3.6	7.9	6.2	2.8	4.4	4.7	3.5	7.7	3.8	3.8	7.7	6.6	
	2015	309	8.8	8.4	8.2	7.9	7.7	7.5	7.5	6.7	4.5	8.6	8.5	8.4	7.6	7.7	7.1	6.9	6.7	4.0	2.7	3.2	3.5	3.3	6.8	3.5	3.7	7.8	6.1	2.6	3.2	3.5	3.5	7.1	3.9	3.7	7.9	6.2	
Non-SC users:																																							
	2014	52	9.1	8.3	8.0	8.3	7.8	7.8	8.6	6.4	7.5	9.1	8.5	8.6	8.1	8.3	8.8	6.8	7.4	2.3	2.7	3.1	2.4	5.3	2.7	2.7	7.1	3.9	1.7	2.0	2.4	1.9	5.6	2.2	1.7	6.6	3.4		
	2015	71	9.3	8.6	8.8	8.4	7.6	8.3	8.7	5.9	5.7	8.9	8.9	8.7	8.4	7.8	7.9	8.4	6.4	5.7	1.9	2.4	2.5	2.4	6.4	2.7	2.3	7.1	5.2	1.4	1.7	2.1	2.1	5.7	2.5	1.6	6.8	4.6	
	2014	132	8.2	8.9	8.9	8.6	7.6	8.2	6.6	7.1	4.7	8.3	8.7	8.5	7.8	7.3	7.6	6.7	6.9	4.6	3.1	3.1	3.1	3.3	6.8	3.5	4.1	7.9	6.0	3.3	3.3	3.5	3.6	6.8	3.8	4.1	7.7	6.1	
	2015	29	9.4	8.9	8.9	7.3	8.1	6.9	7.2	6.4	4.0	9.4	8.4	8.0	7.3	7.3	7.0	6.4	3.9	2.3	3.1	3.4	3.7	6.7	4.0	4.6	7.9	6.1	1.8	3.6	3.9	3.3	7.7	4.0	3.9	9.0	6.0		

<b>Age groups:</b>																																						
16-29	537	554	8.7	8.4	8.2	7.8	7.4	7.3	7.3	6.4	4.3	8.6	8.6	8.5	7.5	7.5	7.1	7.1	6.5	4.1	2.5	3.4	3.9	3.3	7.0	3.7	3.6	7.6	6.0	2.5	3.2	3.5	3.3	7.3	3.6	3.5	7.7	6.1
30 plus	297	280	8.7	8.4	8.1	8.2	7.7	7.9	7.5	6.8	5.3	8.7	8.5	8.4	8.2	7.9	7.7	7.2	6.7	5.2	2.7	3.1	3.5	3.2	6.5	3.4	3.5	7.9	5.5	2.7	3.2	3.4	3.2	6.1	3.6	3.5	7.7	5.5
<b>Employment status:</b>																																						
Employed	350	352	9.0	8.5	8.3	7.9	7.6	7.4	7.3	6.4	4.6	8.8	8.7	8.5	7.8	7.8	7.3	7.3	6.6	4.7	2.3	3.0	3.4	3.1	6.7	3.4	3.5	8.0	5.8	2.2	3.0	3.3	3.2	6.8	3.6	3.2	7.9	5.7
Unemployed	430	425	8.5	8.3	8.0	8.0	7.4	7.6	7.3	6.7	4.7	8.4	8.5	8.3	7.7	7.5	7.3	6.7	6.8	4.2	2.9	3.6	4.0	3.4	6.9	3.8	3.7	7.5	5.9	2.9	3.4	3.7	3.3	7.0	3.6	3.8	7.6	6.1
Student	52	58	8.8	8.3	7.8	7.8	7.8	7.2	7.4	6.2	4.4	8.9	8.6	8.3	8.0	7.7	7.1	7.3	6.4	4.6	1.5	3.0	3.7	3.1	7.3	3.3	2.8	7.5	5.9	1.9	2.8	2.9	3.3	6.8	3.4	2.7	7.2	6.4
<b>Gender:</b>																																						
Female	119	116	8.5	8.6	8.1	8.3	7.7	7.9	7.7	6.9	4.9	8.3	8.7	8.6	7.9	7.5	7.4	7.4	7.1	4.4	2.7	2.8	3.1	2.8	6.6	3.0	3.3	7.1	5.7	3.0	2.9	3.2	3.0	7.0	3.3	3.3	7.5	6.2
Male	714	715	8.8	8.4	8.2	7.9	7.5	7.4	7.3	6.5	4.6	8.7	8.6	8.4	7.7	7.7	7.3	7.1	6.6	4.5	2.5	3.4	3.8	3.4	6.9	3.7	3.6	7.8	5.9	2.5	3.3	3.5	3.3	6.9	3.7	3.5	7.7	5.9
<b>Ethnicity:</b>																																						
Non-Maori	477	487	8.7	8.4	8.2	7.8	7.4	7.3	7.0	6.5	4.5	8.6	8.6	8.5	7.6	7.6	7.2	6.9	6.6	4.5	2.5	3.4	3.8	3.5	6.7	3.8	3.7	8.0	5.8	2.4	3.2	3.4	3.3	7.0	3.7	3.5	8.0	6.0
Maori	356	346	8.8	8.4	8.1	8.1	7.7	7.7	7.8	6.7	4.8	8.6	8.6	8.4	7.9	7.7	7.4	7.5	6.7	4.5	2.7	3.2	3.6	2.9	7.0	3.2	3.3	7.3	5.9	2.7	3.3	3.5	3.1	6.7	3.5	3.4	7.2	5.9
<b>Mental health status:</b>																																						
Suffered mental health illness ever in the past	290	245	8.7	8.4	8.1	7.9	7.5	7.6	7.1	6.9	4.5	8.5	8.7	8.5	7.8	7.5	7.3	6.9	7.0	4.2	2.6	3.4	3.8	3.5	6.9	3.7	3.7	8.0	5.9	2.7	3.5	3.7	3.4	7.0	3.7	3.7	7.9	5.8
Never suffered mental health issues	533	584	8.7	8.4	8.1	7.9	7.6	7.4	7.5	6.4	4.7	8.7	8.6	8.4	7.7	7.7	7.3	7.3	6.6	4.6	2.6	3.3	3.7	3.2	6.8	3.5	3.5	7.6	5.9	2.5	3.0	3.4	3.2	6.9	3.6	3.4	7.6	6.0
<b>Education:</b>																																						
Compulsory high school education completed	475	524	8.8	8.4	8.1	7.9	7.5	7.4	7.3	6.6	4.7	8.7	8.6	8.4	7.8	7.7	7.3	7.1	6.7	4.6	2.3	3.2	3.7	3.3	6.8	3.6	3.5	7.9	5.6	2.5	3.3	3.6	3.4	7.0	3.7	3.7	8.0	6.0
Compulsory high school education not completed	357	305	8.6	8.5	8.2	8.0	7.5	7.7	7.4	6.5	4.5	8.4	8.6	8.5	7.7	7.6	7.2	7.2	6.7	4.3	2.9	3.4	3.8	3.3	6.9	3.5	3.7	7.5	6.2	2.5	3.0	3.3	2.9	6.8	3.3	3.1	7.2	5.9

### Perceived health risk of approved SC and approved PP compared to other drugs

In 2014 and 2015, the total sample perceived approved SC as riskier to health than (natural) cannabis (2014: 8.1 vs 4.6,  $p < 0.0001$ ; 2015: 8.4 vs 4.5,  $p < 0.0001$ ), alcohol (2014: 8.1 vs 6.6,  $p < 0.0001$ ; 2015: 8.4 vs 6.7,  $p < 0.0001$ ), approved PP (2014: 8.1 vs 7.5,  $p < 0.0001$ ; 2015: 8.4 vs 7.3,  $p < 0.0001$ ), tobacco (2014: 8.1 vs 7.5,  $p < 0.0001$ ; 2015: 8.4 vs 7.6,  $p < 0.0001$ ) and ecstasy (2014: 8.1 vs 7.3,  $p < 0.0001$ ; 2015: 8.4 vs 7.1,  $p < 0.0001$ ) (Table 2). In 2014, methamphetamine was considered riskier than approved SC (8.7 vs 8.1 health risk score,  $p < 0.0004$ ). In 2015, the difference between methamphetamine (8.6) and approved SC (8.4) was not statistically significant (Table 2).

In 2014, both occasional and frequent SC users thought that approved SC were riskier to health than alcohol (occasional SC: 8.2 vs 6.7,  $p < 0.0001$ ; frequent SC: 7.5 vs 6.4,  $p = 0.0011$ ) and cannabis (occasional SC: 8.2 vs 4.5,  $p < 0.0001$ ; frequent SC: 7.5 vs 3.9,  $p < 0.0001$ ), but safer than methamphetamine (occasional: 8.2 vs 8.8,  $p = 0.0362$ ; frequent SC: 7.5 vs 8.5,  $p = 0.0037$ ). Occasional SC users also thought that approved SC were riskier than ecstasy (8.2 vs 7.5,  $p = 0.0360$ ).

In 2015, occasional SC users considered approved SC products riskier than cannabis (8.4 vs 4.0,  $p < 0.0001$ ), alcohol (8.4 vs 6.7,  $p < 0.0001$ ), ecstasy (8.4 vs 6.9,  $p < 0.0001$ ), approved PP (8.4 vs 7.1,  $p < 0.0001$ ), unapproved PP (8.4 vs 7.6,  $p < 0.0001$ ) and tobacco (8.4 vs 7.7,  $p = 0.0001$ ), but made no distinction between approved SC and methamphetamine (8.6). In 2015, frequent SC users thought approved SC were riskier than cannabis (7.9 vs 3.8,  $p < 0.0001$ ), alcohol (7.9 vs 6.6,  $p = 0.0303$ ) and approved PP (7.9 vs 6.5,  $p = 0.0310$ ), but made no distinction between approved SC and methamphetamine (8.4) (Table 2).

In both years the total sample thought that regularly using approved PP was safer than using approved SC products (2014: 7.5 vs 8.1,  $p < 0.0001$ ; 2015: 7.3 vs 8.4,  $p < 0.0001$ ), unapproved SC products (2014: 7.5 vs 8.4,  $p < 0.0001$ ; 2015: 7.3 vs 8.6,  $p < 0.0001$ ) and methamphetamine (2014: 7.5 vs 8.7,  $p < 0.0001$ ; 2015: 7.3 vs 8.6,  $p < 0.0001$ ), but riskier than alcohol (2014: 7.5 vs 6.6,  $p < 0.0001$ ; 2015: 7.3 vs 6.7,  $p < 0.0001$ ) and cannabis (2014: 7.5 vs 4.6,  $p < 0.0001$ ; 2015: 7.5 vs 4.5,  $p < 0.0001$ ).

### Perceived social acceptability of approved SC and approved PP compared to other drugs

In 2014, the total sample perceived approved SC to be less socially acceptable than alcohol (3.7 vs 7.7 social acceptability score,  $p < 0.0001$ ), tobacco (3.7 vs 6.8,  $p < 0.0001$ ) and cannabis (3.7 vs 5.9,  $p < 0.0001$ ), but more acceptable than methamphetamine (3.7 vs 2.6,  $p < 0.001$ ) (Table 2). In 2014, occasional SC users gave the same assessment. Frequent SC users also thought that using approved SC was more acceptable than using unapproved PP (5.1 vs 3.7,  $p = 0.0001$ ) and ecstasy (5.1 vs 3.6,  $p < 0.0001$ ). In 2015, the frequent SC users no longer made this distinction.

In 2015, the total sample, and occasional SC users and frequent SC users shared the view that approved SC were less socially acceptable than alcohol (total sample: 3.5 vs 7.7,  $p < 0.0001$ ; occasional SC: 3.5 vs 7.9,  $p < 0.0001$ ; frequent SC: 4.7 vs 7.7,  $p < 0.0001$ ), tobacco (total sample: 3.5 vs 6.9,  $p < 0.0001$ ; occasional SC: 3.5 vs 7.1,  $p < 0.0001$ ; frequent SC: 4.7 vs 7.7,  $p < 0.0001$ ) and cannabis (total sample: 3.5 vs 5.9,  $p < 0.0001$ ; occasional SC: 3.5 vs 6.2,  $p < 0.0001$ ; frequent SC: 4.7 vs 6.6,  $p = 0.0001$ ), but more socially acceptable than methamphetamine (total sample: 3.5 vs 2.5,  $p < 0.0001$ ; occasional SC: 3.5 vs 2.6,  $p = 0.0001$ ; frequent SC: 4.7 vs 2.8,  $p = 0.0001$ ).

In 2014 and 2015, the total sample considered approved PP less socially acceptable than alcohol (2014: 3.6 vs 7.7,  $p < 0.0001$ ; 2015: 3.6 vs 7.7,  $p < 0.0001$ ), cannabis (2014: 3.6 vs 5.9,  $p < 0.0001$ ; 2015: 3.6 vs 5.9,  $p < 0.0001$ ) and tobacco (2014: 3.6 vs 6.8,  $p < 0.0001$ ; 2015: 3.6 vs 6.9,  $p < 0.0001$ ),

but more socially acceptable than methamphetamine (2014: 3.6 vs 2.6,  $p < 0.0001$ ; 2015: 3.6 vs 2.5,  $p < 0.0001$ ).

Health perceptions of approved SC and PP of different drug user and demographic groups

In 2014, perceptions of the health risks of approved SC were lower among frequent SC users than occasional SC users (7.5 vs 8.2,  $p = 0.0390$ ), cannabis users (7.5 vs 8.8,  $p = 0.0072$ ) and methamphetamine users (7.5 vs 8.9,  $p < 0.0001$ ). In 2015, however, these differences were no longer statistically significant (Table 3).

In 2014, the perceptions of health risks of approved PP were significantly lower among frequent SC users than occasional SC users (6.8 vs 7.5,  $p = 0.0459$ ), methamphetamine users (6.8 vs 8.2,  $p = 0.0002$ ) and cannabis users (6.8 vs 8.3,  $p = 0.0054$ ) (Table 3). Younger participants (16–29 years old) rated the health risks of approved PP lower than older participants (30 years+) (7.3 vs 7.9,  $p = 0.0036$ ). Maori rated the health risks of using approved PP higher than non-Maori (7.7 vs 7.3,  $p = 0.0448$ ).

In 2015, the health risk perceptions of approved PP continued to be significantly lower among frequent SC users than cannabis users (6.5 vs 7.9,  $p = 0.0256$ ), and among younger compared to older participants (7.1 vs 7.7,  $p = 0.0081$ ). In 2015 only, health perceptions of approved PP were significantly lower among frequent SC users than users of legal drugs (6.5 vs 8.3,  $p = 0.0182$ ).

**Table 2: Comparisons of mean scores for approved SC vs other drugs as assessed by the total sample, frequent SC users and occasional SC users**

		Difference in mean health perceptions						Difference in mean social acceptability					
		2014			2015			2014			2015		
Drugs compared		total sample	Frequent SC	Occasional SC	total sample	Frequent SC	Occasional SC	total sample	Frequent SC	Occasional SC	total sample	Frequent SC	Occasional SC
SC approved	SC unapproved	0.26	0.55	0.22	0.17	0.49	0.09	0.42	0.89	0.32	0.27	0.30	0.29
	alcohol	1.59*	1.08*	1.42*	1.74*	1.23*	1.78*	3.99*	2.80*	4.34*	4.22*	2.93*	4.39*
	cannabis	3.51*	3.62*	3.66*	3.96*	4.11*	4.44*	2.13*	1.10*	2.56*	2.46*	1.90*	2.68*
	tobacco	0.62*	0.42	0.41	0.78*	0.58	0.77*	3.10*	2.41*	3.33*	3.43*	2.99*	3.58*
	PP approved	0.66*	0.73	0.65	1.12*	1.32*	1.32*	0.15	0.80	0.02	0.11	0.99	0.34
	PP unapproved	0.22	0.14	0.21	0.67*	0.61	0.85*	0.45	1.37*	0.23	0.22	1.24	0.03
	ecstasy	0.80*	0.60	0.68*	1.28*	0.93	1.53*	0.17	1.46*	0.15	0.00	0.97	0.21
	methamphetamine	0.57*	1.01*	0.66*	0.21	0.51	0.18	1.16*	2.75*	0.75*	0.93*	3.22*	0.89*

\* - statistically significant differences

Social acceptability of approved SC and PP of different drug user and demographic groups

In 2014 and 2015, frequent SC users rated the social acceptability of using approved SC significantly higher than occasional SC users (2014: 5.1 vs 3.5,  $p < 0.0001$ ; 2015: 4.7 vs 3.5,  $p = 0.0019$ ), cannabis users (2014: 5.1 vs 2.5,  $p < 0.0001$ ; 2015: 4.7 vs 2.1,  $p < 0.0001$ ), users of legal drugs only (2014: 5.1 vs 3.1,  $p = 0.0013$ ; 2015: 4.7 vs 2.4,  $p = 0.0009$ ) and methamphetamine users (2014: 5.1 vs 3.1,  $p < 0.0001$ ; 2015: 4.7 vs 3.5,  $p = 0.0163$ ) (Table 3).

In 2015, the social acceptability of approved SC was also significantly higher among occasional SC users than users of natural cannabis (3.5 vs 2.1,  $p = 0.0006$ ). In 2014, the social acceptability of SC was higher among males than females (3.8 vs 3.1,  $p = 0.0168$ ), and among unemployed compared to employed participants (4.0 vs 3.4,  $p = 0.0231$ ). In 2015, there was no statistically significant difference in assessments of the social acceptability of approved SC among the different sociodemographic groups.

In 2014, the frequent SC users rated the social acceptability of approved PP higher than occasional SC users (4.3 vs 3.5,  $p = 0.0445$ ), cannabis users (4.3 vs 2.7,  $p = 0.0039$ ) and users of legal drugs only (4.3 vs 2.7,  $p = 0.0227$ ). In 2014, Maori participants rated the social acceptability of using approved PP lower than non-Maori (3.2 vs 3.8,  $p = 0.0072$ ). Males rated it higher than females (3.7 vs 3.0,  $p = 0.0421$ ).

In 2015, frequent SC users continued to have higher social acceptability perceptions of approved PP compared to cannabis users (3.8 vs 2.5,  $p = 0.0385$ ). However, the differences between frequent and occasional SC users, and frequent SC users and legal drugs only users were no longer statistically significant (Table 3). In addition, social acceptability assessments of approved PP by occasional SC users were higher than those of legal drugs only users (3.9 vs 2.5,  $p = 0.0149$ ).

**Table 3: Comparison of mean scores for approved SC and approved PP between frequent SC and other drug users groups**

Drug use groups compared	Difference between mean health perceptions scores				Difference in mean social acceptability scores				
	Approved SC		Approved PP		Approved SC		Approved PP		
	2014	2015	2014	2015	2014	2015	2014	2015	
frequent SC	occasional SC	0.68*	0.58	0.75*	0.58	1.59*	1.22*	0.80*	0.12
frequent SC	legal drugs only	0.56	0.64	1.06	1.79*	1.97*	2.33*	1.56*	1.56
frequent SC	cannabis	1.28*	0.82	1.53*	1.36*	2.63*	2.63*	1.59*	1.28*
frequent SC	ecstasy	1.37	0.65	0.09	0.73	1.71	0.82	0.32	0.21
frequent SC	methamphetamine	1.41*	0.65	1.44*	1.03	1.94*	1.24*	0.80	0.01

\* - statistically significant differences

The impact of regulatory approval of SC and PP on health risk and acceptability perceptions

In 2014 and 2015, the total sample considered using approved SC and approved PP as safer and more socially acceptable than using unapproved SC and PP ( $p < 0.0001$ ) (Table 4). The samples of regular and occasional SC users generally agreed with this view. In 2015, however, occasional SC users did not think there was any difference in the health risks of approved (8.4) and unapproved SC (8.5), and frequent SC users did not think there was any difference in the social acceptability of approved SC (5.1) and unapproved SC (4.2), and approved PP (4.3) and unapproved PP (3.7) (Table 5).

Other drug users, on the other hand, generally did not make any distinction in their assessments of health risks and social acceptability between approved and unapproved SC and PP products. The only exceptions were in 2014 when methamphetamine users thought approved PP were safer than unapproved PP (8.2 vs 8.6,  $p = 0.0077$ ), and in 2015 when natural cannabis users

thought approved PP were safer (7.9 vs 8.4,  $p=0.0009$ ) and more socially acceptable than unapproved PP (2.5 vs 2.1,  $p=0.037$ ).

Most sociodemographic groups considered using approved SC and approved PP as safer and more socially acceptable than using unapproved SC and PP, and this trend was clearest among younger participants, males and those who had completed high school education ( $p<0.0001$  for both PP and SC measures for health risk and social acceptability in both years). However, in general females did not consider approved products safer or more socially acceptable (except in the case of the perceived health risks of approved vs unapproved SC (8.1 vs 8.6,  $p=0.0017$ ) and social acceptability for approved vs unapproved PP (3.0 vs 2.8,  $p=0.0007$ ) in 2014).

**Table 4: Difference in mean scores of approved and unapproved SC and PP**

	Difference between mean health perceptions scores				Difference in mean social acceptability scores			
	Approved and unapproved SC		Approved and unapproved PP		Approved and unapproved SC		Approved and unapproved PP	
	2014	2015	2014	2015	2014	2015	2014	2015
Total sample	0.27**	0.17**	0.43**	0.41**	0.40**	0.24**	0.28**	0.30**
<u>SC users:</u>								
Frequent SC users	0.50*	0.49*	0.61**	0.71*	0.90**	0.30	0.54**	0.17
Occasional SC users	0.28*	0.10	0.38**	0.37**	0.37**	0.22**	0.19*	0.34**
<u>Non-SC users:</u>								
Alcohol/tobacco users	0.17	0.03	0.38	0.27	0.10	0.39	0.21	0.29
Cannabis users	0.05	0.27	0.13	0.55*	0.10	0.13	0.22	0.34*
Methamphetamine users	0.08	0.11	0.35*	0.30	0.09	0.17	0.23	0.18
Ecstasy users	0.08	0.00	0.52	0.70	0.26	0.44	0.23	0.63
<u>Age groups:</u>								
16-29	0.25**	0.20**	0.52**	0.40**	0.41**	0.26**	0.33**	0.28**
30 plus	0.31*	0.11	0.24**	0.44**	0.37*	0.20*	0.19	0.33**
<u>Employment status:</u>								
Employed	0.20*	0.16*	0.43**	0.47**	0.37**	0.29**	0.29*	0.38**
Unemployed	0.29*	0.15*	0.40**	0.30*	0.38**	0.22*	0.28**	0.26**
Student	0.53	0.31	0.56	0.80*	0.74*	0.05	0.21	0.09
<u>Gender:</u>								
Female	0.48*	0.15	0.36	0.49	0.22	0.22	0.36*	0.16
Male	0.23**	0.17**	0.44**	0.40**	0.43**	0.24**	0.27**	0.32**
<u>Ethnicity:</u>								
Non-Maori	0.28**	0.14*	0.47**	0.37**	0.39**	0.24**	0.33**	0.29**
Maori	0.25*	0.21*	0.36**	0.47**	0.40**	0.23*	0.22	0.32**
<u>Mental health status:</u>								
Suffered mental health illness ever in the past	0.29*	0.13	0.37**	0.43**	0.38*	0.13	0.27*	0.24*
Never suffered mental health issues	0.27**	0.19*	0.47**	0.41**	0.41**	0.28**	0.29**	0.33**
<u>Education:</u>								
Compulsory high school education completed	0.26**	0.19**	0.48**	0.40**	0.41**	0.23**	0.34**	0.28**
Compulsory high school education not completed	0.28**	0.12	0.36**	0.42**	0.38**	0.24*	0.20*	0.31**

\* - statistically significant differences at  $p<0.01$  level

\*\* - statistically significant differences at  $p<0.001$  level

## **Appendix K: Letter published in *Addiction*: Is the recent ban on animal testing of legal high products a fatal blow to the development of a legal market for ‘low-risk’ psychoactive products in New Zealand?**

Rychert, M., & Wilkins, C. (2015). Is the recent ban on animal testing of legal high products a fatal blow to the development of a legal market for ‘low-risk’ psychoactive products in New Zealand? [Letter] *Addiction*, 110(4), 713-714. Doi: 10.1111/add.12853

In July 2013, New Zealand established the world’s first regulated legal market for new psychoactive substances (NPS) (i.e. ‘legal highs’) with the passing of the *Psychoactive Substances Act* (PSA) [1,2]. This approach has received considerable international attention as a possible solution to the ongoing problems with NPS which could be adopted in other countries [3-8]. The UK NPS Expert Panel recently called on the UK Government to monitor the New Zealand regime, including its public health impacts and the mechanisms used to identify “low risk” psychoactive products [9].

Implementation of the PSA has proven to be controversial. The transitory interim regime which allowed a limited number of existing products continue to be sold subject to new retail restrictions (i.e. R18, no sales from convenience stores, limited advertising) [10], was brought to an abrupt end by the passage of the *Psychoactive Substances Amendment Act* (PSAA) [11] on the 7th May 2014, following reports of adverse effects from products [12].

While the ending of the interim regime was widely viewed as a set-back, a potentially more fatal impact of the PSAA was the decision to prohibit the use of animal tests (including tests conducted overseas [13,14]) to demonstrate products are “low risk” and thus able to be approved for legal sale [15,16]. The animal testing ban followed public protests against the harming of animals for the purpose of testing products with no therapeutic effect [12,14]. The Psychoactive Substances Regulatory Authority (PSRA) has gone so far as to state that ‘it is unlikely that a product can be shown to pose no more than a low risk of harm without the use of animal testing’; suggesting the PSA was now unworkable [13]. Other commentators have expressed greater optimism. The legal high industry lobby group recently predicted there is an ‘over 80% chance’ that an approved psychoactive product will be available for sale by the end of 2015 [17].

Our reading of the PSAA and engagement with key stakeholders suggests four possible ways forward: (1) modify the animal testing ban (e.g. allow testing on select species); (2) wait until validated non-animal models are available to assess all aspects of product safety crucial to demonstrate low risk; (3) challenge the rejection of product applications in court by questioning whether the animal testing ban is consistent with the stated purpose of the PSA to create a regulated NPS market; (4) ‘creatively comply’ with the law by providing required evidence of low risk without direct reference to animal tests. This may involve supporting a product application with data from human clinical trials following animal tests (completed overseas), without directly referencing the animal testing; and may entail application for approval of a pharmaceutical product with psychoactive effects which already has extensive safety data (i.e. a ‘failed medicine’).

The PSRA has signalled that regulations for the full regime will be finalised by mid-2015 so there is growing urgency for a political, regulatory or judicial solution to the impasse. We are continuing to investigate and assess the feasibility of the above options. What is clear from the

short-lived interim regime is that the financial returns of a legal market are considerable (estimated \$140 million annual retail sale [12]) and this may focus decision makers' minds.

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## **Appendix L: Letter published in *Addiction*: Recent developments with the New Zealand regulated market approach to ‘low-risk’ psychoactive products.**

Wilkins, C., and Rychert, M. (2017) Recent developments with the New Zealand regulated market approach to ‘low-risk’ psychoactive products. *Addiction*, 112: 34–36. doi: [10.1111/add.13495](https://doi.org/10.1111/add.13495).

Reuter & Pardo [1] highlight clearly the conceptual difficulties and practical enforcement issues inherent in the ‘blanket ban’ approach to ‘legal highs’, as enacted recently by the United Kingdom's *Psychoactive Substances Act 2016* (UK PSA) [1]. Reuter & Pardo's critique of the UK PSA is placed in a wider context by reviewing other recent policy approaches to ‘legal highs’, including New Zealand's regulated market regime as established by the New Zealand *Psychoactive Substances Act 2013* (NZ PSA) [2, 3]. In their discussion of the NZ PSA, Reuter & Pardo [1] note, rightly, the challenges of establishing what constitutes a “low risk” product, and hence one able to be approved for legal sale, as responsible for the delays with implementing the full NZ PSA regime [4, 5]. There has recently been further progress with this aspect of the NZ PSA regulatory framework. In November 2014, the Psychoactive Substances Regulatory Authority (PSRA) released a detailed discussion document outlining the procedural framework for product applications, assessments and appeals under the NZ PSA [6]. The PSRA proposed that the International Conference on Harmonisation (ICH) Standards should be followed to demonstrate the safety of psychoactive products, and the United States Food and Drug Administration ‘Guidance for Industry: Assessment of Abuse Potential of Drugs’ [7] be used as the guide for investigations into the abuse potential of products [8]. As a consequence, the PSRA announced that the NZ PSA regulatory framework was now ‘complete’ and has called for product applications. However, as of May 2016, no product applications had been received [9].

Reuter & Pardo [1] also touch upon the issue of the ban of the use of animals to test the safety of psychoactive products as another reason for the problems with the NZ PSA. The issue of opposition to animal testing of the safety of recreational psychoactive products is likely to go beyond the NZ PSA. It could potentially afflict other regulatory regimes for recreational drugs, such as the legal cannabis regimes in the United States and Uruguay which may also, at some point, want to test the safety of the cannabis products on sale legally. Currently, there is a well-organized popular opposition to the harming of animals to determine the safety of what is perceived to be trivial consumer products, as witnessed by bans of animal testing of cosmetics in Europe and recently in New Zealand in May 2015. The fact that recreational psychoactive products have no therapeutic benefit means they are particularly vulnerable to challenges on these grounds [6]. Reflecting the level of popular opposition to animal testing of purely recreational psychoactive products, the New Zealand government imposed a comprehensive ban on animal testing of psychoactive products in May 2014, including animal trials conducted in other countries and even all past animal test studies [10]. The PSRA responded that they were ‘unaware of any suitable non-animal alternatives for assessing the pharmacokinetics, metabolism, reproductive toxicity or addiction potential of a substance’, and went on to conclude that: ‘it is unlikely that a product can be shown to pose no more than a low risk of harm without the use of animal testing’, suggesting that the PSA is now unworkable [8]. Further investigation has suggested there are a number of possible strategies to ‘work around’ the animal test ban, but these would require tacit political support and some acquiescence from the PSRA [6]. A ‘failed’ pharmaceutical product which has not achieved the required therapeutic

threshold, but which happens to have a psychoactive effect and already has complete animal and human trial data, may have the best chance to gain an approval under the current circumstances in New Zealand [6].

Reuter & Pardo [1] note, rightly, that the NZ PSA was uniquely innovative compared to the reactive prohibition approaches adopted in other countries. The reality is that the NZ Government has withdrawn all interim psychoactive product approvals granted under the NZ PSA; there is now essentially a 'blanket ban' on all psychoactive substances (i.e. all unlicensed 'psychoactive' products are banned by default under the NZ PSA). This irony has not escaped some people who argue the PSA was a blanket ban by stealth [11]. In addition, the NZ PSA also imposes administrative penalties for the possession of unapproved psychoactive products, and hence is actually somewhat harsher than the recently enacted UK PSA, which does not punish possession of NPS for personal use (unless it is possession in custodial institution such as prison, s. 9 UK PSA) [12]. Interestingly, although the end result in New Zealand has been a 'blanket ban', essentially the same as in the United Kingdom, the fact that the PSA was touted as a regulatory approach means the imposition of the 'blanket ban' occurred without anywhere near the same level of controversy as seen in the United Kingdom.

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## **Appendix M: Co-authored book chapter: “Exploring novel policy responses to NPS and ‘legal highs’ in New Zealand, Poland, Republic of Ireland & the United Kingdom”**

Wilkins, C., Rychert, M., Byrska, B., Van Hout, M., Corazza, O., & A.Roman-Urrestarazu (2017). “Exploring novel policy responses to NPS and ‘legal highs’ in New Zealand, Poland, Republic of Ireland & the United Kingdom”. *Novel Psychoactive Substances. Policy, Economics and Drug Regulation*. Ed. Ornella Corazz & Andres Roman-Urresterazu. Springer Nature, 2017.

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### **Abstract**

A number of countries including New Zealand, Poland, the Republic of Ireland and the United Kingdom, have experienced particularly dynamic markets for new psychoactive substances (NPS) and, as a result, have responded with innovative legislative and policy approaches. Poland, Ireland, and recently the UK, have established broad catch-all definitions of psychoactive products in order to impose blanket bans on all current and future psychoactive products. There is some evidence from Poland and Ireland to suggest these approaches may have reduced the use and harm from NPS over a number of months. However, sellers and users adapted to these controls over time by purchasing NPS from websites based overseas and from the black market, resulting in increasing use. Furthermore, the banning of many original NPS compounds may have resulted in the use of more potent and toxic replacement compounds. In contrast, New Zealand adopted a pre-market approval regime for psychoactive products, similar to the regimes commonly operated for medicines, in an attempt to undermine the grey market for high risk products, ensure products available on the legal market were low risk, and provide consumers with accurate information about the potency, ingredients and risks of products. The implementation of this new regime proved to be controversial and, following ongoing reports of adverse effects from products and social nuisance around retail outlets, was brought to an abrupt halt. While the legislation for this regulatory regime remains in force, no further product approvals have been made and it is unclear whether there is political will to continue with this innovative approach.

### **Introduction**

Over the past five years or so there has been an unprecedented rise in the number of new psychoactive substance (NPS) drugs detected worldwide which mimic the effects of traditional illegal drugs. These novel compounds are often sold as so called “legal highs”, as they are generally not controlled under international United Nation (UN) Drug Conventions. However, increasingly they are being controlled under domestic laws in many countries, and are beginning to be included in the UN conventions (EMCDDA, 2016; UNODC, 2016). The number of NPS monitored by the UNODC worldwide increased from 166 in 2009 to 644 in 2015 (UNODC, 2016). Seventy-five new NPS compounds were reported for the first time in 2015 (UNODC, 2016). The emergence of NPS has been associated with hospital emergency department admissions, psychosis and deaths. The UNODC recently concluded NPS pose a global public health risk and a significant challenge to the international drug control system (UNODC, 2014).

A number of countries, including the Republic of Ireland, Poland, United Kingdom (UK) and New Zealand, have faced particularly dynamic NPS markets with a growing range of ‘legal high’

products sold from an increasing number of physical legal retail outlets. The rapid rise in use of these products, with related clusters of acute poisonings, psychosis and other drug related harm, compelled the authorities in these countries to pursue innovative policy responses to address this new drug market. This chapter explores the emergence of this new wave of drug use and subsequent legislative and other policy responses in these four countries.

### **NPS in the Republic of Ireland**

A new recreational drug phenomenon emerged in the Republic of Ireland in 2005 with the advent of 'legal highs' sold in "headshops"<sup>1</sup> (Kavanagh & Power, 2014). By May 2010, the number of headshops had increased to 102, equating to one shop per 45,000 people (Smyth, James, Cullen & Darker, 2015). This new wave of legal drug consumerism occurred at a time of poor street quality in traditional illegal drugs (Van Hout, 2012). Headshop retailers complied with Irish law and marketed products as "legal" and "not for human consumption", despite the products being labelled with drug associated nomenclature (Van Hout, 2012). Examples of product labelling included "Sky High", "Plant food", "M1", and "Miaow Miaow" (Ryall & Butler, 2011; Van Hout & Brennan, 2011a).

Use of these 'legal high' products was not confined to problematic drug users (McElrath & Van Hout, 2011; Van Hout & Bingham, 2012; Van Hout & Brennan, 2011a). Ryall and Butler (2011: 306) reported a headshop owner emphasising the "broad base of customer support for her industry". User decisions to try 'legal high' products were reportedly influenced by 24 hour availability, low price relative to illegal drugs; home delivery, advertising, ability to avoid the illegal drug trade, and the fact that many legal high products could not be detected in standard drug testing assays (this was particularly valued by those on methadone) (McElrath & Van Hout, 2011; Ryall & Butler, 2011; Van Hout & Bingham, 2012; Van Hout & Brennan, 2011a, 2011b, 2011c). Users appeared to perceive these products as safe, with little awareness around risks relating to product toxicity and lack of regulation (Van Hout, 2012). Users often relied on headshop staff for advice around safe consumption (Van Hout, 2012).

The rise in popularity of a diverse range of 'legal highs', especially cathinone derivatives and indole-based cannabimimetics, contributed to political and societal concern in Ireland (Kavanagh & Power, 2014). Clinical concerns centred on NPS as a factor in diagnoses of those presenting with psychosis and suicidal ideation (El-Higaya, Ahmed & Hallahan, 2011; O'Domhnaill & Ni Chleirigh, 2011; Tully, Hallahan & McDonald, 2011; Uhoegbu, Kolshus, Nwachukwu, Guerandel & Maher, 2011). Following user hospitalisations and fatalities, and public attacks on several headshops in 2010, media reporting and public protests ensued (Radio Telefís Éireann, 2010).

A number of headshop owners formed the Alternative Traders Ireland (ATI) association in 2010, to represent the interests of the commercial sector in Ireland and liaise with the Government, media and other concerned parties. They were keen to promote regulation and corporate social responsibility via an ethical code of practice for the sale of 'legal highs' (for example voluntary restrictions on the sale of these products to those under 18 years, in school uniform, intoxicated, through hatches, and on opening hours) (Ryall & Butler, 2011). Community lobbying and media reporting ultimately contributed to new legislation to prohibit these products (Ryall & Butler, 2011; Van Hout, 2012; Van Hout & Brennan, 2011a). Prior to these controls, headshops were opening at a rate of one per week in January 2010 (Van Hout, 2012).

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<sup>1</sup> A headshop is a retail outlet which specialises in drug paraphernalia related to consumption of cannabis, other recreational drugs, and New Age herbs, as well as counterculture art, magazines, music, clothing and home decor.

### *The Irish Psychoactive Substances Act 2010*

The Irish Criminal Justice Psychoactive Substances Act 2010 (I-PSA) provided a novel, non-traditional approach to addressing the growing supply of NPS. The I-PSA introduced an innovative “catch-all” law applicable to all psychoactive products not explicitly prohibited under the *Misuse of Drugs Act 1977*. The definition of psychoactivity included a threshold of “significant” mental disturbance or change (EMCDDA, 2015).

The IPSA made it illegal to sell, import, export or advertise such psychoactive products. To give effect to this decision, on the same day the Minister for Health and Children signed the following companion amendments: *Misuse of Drugs (Amendment) Regulations 2010*, *the Misuse of Drugs (Designation) (Amendment) Order 2010*, and the *Misuse of Drugs (Exemption) (Amendment) Order 2010*. Under these statutory instruments, 200 NPS compounds (i.e. benzylpiperazine derivatives, mephedrone, synthetic cannabinoids, methylone and related cathinones, GBL and 1, 4 BD, ketamine, Tapentadol) were declared controlled drugs (Connolly, 2012; Long, 2010). The Garda Síochána (Irish police) and Irish courts were given powers to prohibit the sale of these psychoactive substances in the event that such substances were not on the listing advised under the *Misuse of Drugs Act*, and if product packaging represented them, as frequently the case, as “not for human consumption” (Van Hout, 2012).

Following this legislation, headshop numbers declined from 112 in 2009 to just 12 by September 2010 (Smyth, et al., 2015). On the 1st of November 2011, the then Minister of State with responsibility for Drugs Strategy, approved an Order declaring an additional 60 NPS compounds (i.e. further cathinone substances, naphthylpyrovalerone and related substances, synthetic cannabis-type substances, dimethocaine and desethyl dimethocaine, desoxypiprado, aminotetralins and aminoindans, fluorotropacocaine, salvinorin mitragynine and 7-hydroxymitragynine) to be controlled drugs under the *Misuse of Drugs Acts*. Ryall and Butler (2011) speculated at the time that this extreme drug policy response could be threatened by legal loopholes and challenges on constitutional grounds, and that further regulations would be required to prevent displacement of NPS into underground illicit drug markets.

Indeed, on the 10<sup>th</sup> of March 2015, the *Misuse of Drugs (Amendment) Act 2015* (an emergency legislation), was enacted following a Court of Criminal Appeal ruling that legislation banning the possession of more than 100 drugs (including certain psychoactive substances) was unconstitutional due to a legislative technicality. Consequently, for one day (11 March, 2015) many headshop psychoactive substances and an assortment of other synthetic drugs, including amphetamine, MDMA, Khat and ketamine, were legal to possess in Ireland. The following day the new legislation (*Misuse of Drugs (Amendment) Bill*) was enforced (Health Research Board, 2016). More recently on July 21, 2016, the *Misuse of Drugs (Amendment) Bill 2016* was passed by the Irish government. It included a list of new substances to be controlled, such as prescription medicines (Zopiclone, Zaleplon, Lisdexamfetamine, Phenazepam); the psychedelic phenethylamine derivatives 25B-NBOMe, 25C-NBOMe; MT-45, a substance with morphine-like effects; the psychostimulant, 4,4'-DMAR; and synthetic cannabinoids MDMB-CHMICA, 5F-AKB-48 and 5F-PB-22.

### *Impact of the new legislation*

Pre-legislative studies suggested legal high users in Ireland would not be deterred by the impending legislative controls, and reported stockpiling of products (particularly Mephedrone) and accessing of product from online retailers (McElrath & Van Hout, 2011; Van Hout & Brennan, 2011a, 2011b). Small-scale post legislative studies found a “temporary displacement” with some users ceasing use and others switching back to the traditional illegal street drugs (McElrath &

Van Hout, 2011; Van Hout & Brennan, 2011a, 2011b). Kavanagh and Power (2014) found a reduction in post-mortem blood samples testing positive for cathinone derivatives from 2010 to 2012, and decreases in presence of cathinone derivatives in urine samples of methadone programme patients from 2010 to 2011. Several studies found the legislative controls had some positive results, with small scale studies reporting reduced prevalence of NPS use in cohorts of problematic drug users: high risk youth attending services (Smyth, et al., 2015); and treated heroin dependent adults (O’Byrne, Kavanagh, McNamara & Stokes, 2013).

However, more recent surveys suggest increasing NPS use in Ireland. The EUROBAROMETER (European Commission, 2014) found the use of ‘legal highs’ among young persons (15-24 years) in Ireland increased from 16% in 2011 to 22% in 2014. Public health challenges continue in the form of a spate of hospitalisations and fatalities (2012-2016) due to consumption of  $\alpha$ -PVP, PMMA, 2C-B, 2CP and 2CI, and its derivative 25I-NBOMe. Drug treatment uptake related to NPS remains low, with only 113 treatment cases involving synthetic cannabis reported since 2009.

### **NPS in Poland**

“Headshops” and websites selling ‘legal highs’ containing NPS emerged in Poland in 2008. The legal high products sold were marketed as legal alternatives to controlled recreational drugs and featured attractive packaging and catchy names, which lacked information regarding their ingredients and dosage. Some products were labelled as “not intended for human consumption” so vendors could avoid responsibility for their potential harmful consequences. Legal high products were labelled as collectibles, bath salts, incense, plant fertilizer, religious ritual products, kindling for the grill, etc., all the while being advertised as legal alternatives to illegal psychoactive substances.

The number of headshops selling NPS in Poland expanded rapidly, until by 2010 more than 1,000 were in business. The proportion of Polish youth aged 18-19 who reported ever using an NPS increased from 3.5% in 2008 to 11.0% in 2010 (Jabłoński & Malczewski, 2014). The growing number of headshops and poisonings related to these products, including fatal, attracted considerable media attention which compelled a response from national agencies to restrict their availability (Dąbrowska & Bujalski, 2013; Zakrzewski, 2009). The first drug law amendment to address the problem was adopted as early as March 2009, but it was not until October 2010 that Poland adopted a systemic response.

A 2013 survey found the closure of shops selling these products had an impact, with the prevalence of NPS among youth falling to 5% in 2013 (Jabłoński & Malczewski, 2014). The European Union survey of young people aged 15-24 (‘Eurobarometer’) found NPS use in Poland remained steady at 9% in 2011 and 8% in 2014, while in other EU countries the prevalence of NPS rose (from 5% to 8%) (European Commission, 2011, 2014). However, the ESPAD (European School Survey Project on Alcohol and Other Drugs) survey conducted among young people (aged 15-18) in 2015 found NPS usage in Poland was again higher than average usage in other EU countries (10% vs. 4%) (ESPAD, 2016).

### *Legislative responses*

The emergence of NPS in Poland resulted in several amendments of the *Act of Countering Drug Addiction* (ACDA), the main drug control legislation in Poland. The first, which was enacted in March 2009, extended the list of controlled substances to include 18 NPS, mostly plants (such as salvia divinorum) and two synthetic compounds (BZP and JWH-018) (Polish Parliament, 2009). The second amendment in June 2010 imposed controls on a further 10 synthetic NPS compounds, including mephedrone and nine synthetic cannabinoids (e.g. JWH-073, CP-47,497)

(Polish Parliament, 2010a). However, legal high manufacturers quickly responded by substituting uncontrolled compounds for the newly banned ones.

The ability of legal high manufacturers to circumvent controls based on individual compounds led to the use of a range of administrative measures focusing on headshops to address the problem. In October 2010, the Chief Sanitary Inspector issued a directive closing all headshops selling NPS, as well as NPS wholesalers and manufacturers (Hughes & Malczewski, 2011). This action was effective at closing down these outlets, but the legality of the decision was contested, resulting in subsequent challenges in the Supreme Administrative Court. In the meantime, the government worked on the third amendment to the ACDA with the aim of introducing a new systemic approach to control NPS and prevent any re-opening of NPS retail outlets.

In November 2010, a further Amendment to ACDA and the *Act on State Sanitary Inspectorate* were enacted. This introduced a new definition of “substitute drugs” as “a substance of natural or synthetic origin in any physical state, or a product, plant, fungus, or any of their components containing such a substance used in place of an intoxicating agent or psychotropic substance”. This definition was intended to cover all NPS on the market, if these compounds were not otherwise covered by other legislation. Manufacturing, selling, advertising and promoting “substitute drugs” was prohibited, with enforcement delegated to sanitary inspectors. Sanitary inspectors were given powers, under reasonable suspicion, to withdraw a product containing a “substitute drug” from the market. The penalties for advertising a substitute drug were set as up to one year in prison, while the manufacture and sale of substitute substances was subject to a high administrative fine of between 20,000 and 1,000,000 PLN (€ EUR 5,000 to EUR 250,000) (Polish Parliament, 2010b). The effectiveness of these initiatives has been questioned. It has been argued that the mandate to withdraw *products* rather than substances allowed manufacturers to re-introduce the same NPS compound in a new product with different packaging and a new brand name (Malczewski, 2015).

In April 2011, an additional 24 compounds were identified and added to the list of controlled substances (Polish Parliament, 2011). In the most-recent amendment to the ACDA in April 2015, a further 114 new compounds were scheduled. The amendment also introduced a new definition of a “novel psychoactive substance”, as essentially “a substance of natural or synthetic origin in any physical state that affects the central nervous system”. Furthermore, the list of novel psychoactive substances could now be compiled by the Minister of Health (MOH), requiring much less time than the previous parliamentary scheduling procedures under ACDA (Polish Parliament, 2015). Manufacturing and selling NPS specified in the MOH compiled list is punishable with administrative sanctions. As of October 2016, the MOH list contains 16 compounds, such as AB-CHMINACA, MDMB-CHMICA, 5F-AMB, 2-CMC. This new administrative solution allows the authorities to withdraw compounds from the market, rather than just products (Malczewski, 2015). Possession and use of NPS remained unpenalised.

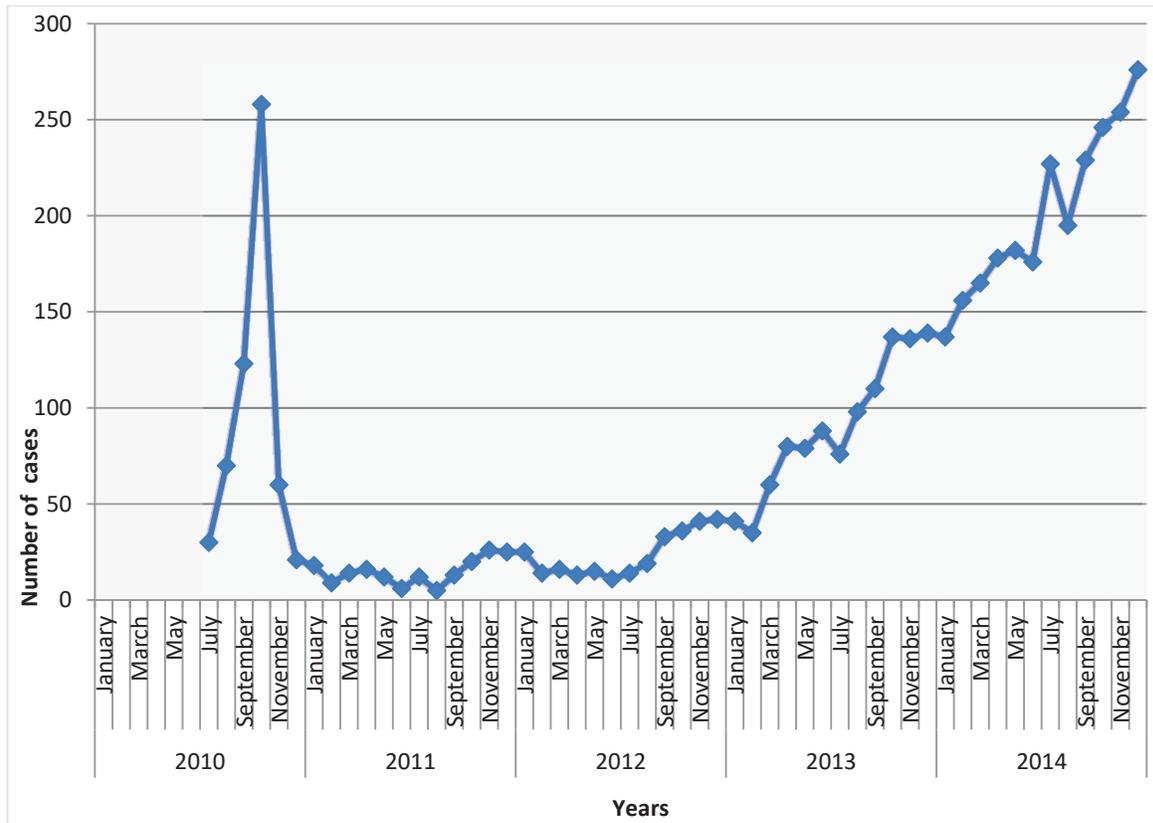
#### *Poisonings caused by NPS*

There have been large fluctuations in the number of poisonings and suspected poisonings related to NPS in Poland over this time (Figure 1). The number of NPS poisonings rose sharply from July to October 2010, with over half of the total number of poisoning for the year reported in October. After the Sanitary Inspector took action to close headshops after October 2010, the number of poisonings fell dramatically to much lower levels in 2011 and 2012. The number of poisonings began to increase again from February 2013, and continued to increase throughout 2014 (Jabłoński & Malczewski, 2014; Kryska, 2016; Posobkiewicz, 2015).

The sale of NPS has also reportedly moved to the Internet and black market (EMCDDA, 2016a). In 2015, more than 7000 cases of suspected poisoning by NPS were reported, including 24

deaths (PAP, 2016). The high number of poisonings in this period may have been a consequence of sellers increasing the concentration of active ingredients in products and reducing prices in an effort to sell their remaining stocks following the last amendment of the ACDA.

**Figure 1:** The number of reported cases or suspected cases of poisoning of NPS between 2010 and 2014 in Poland.



Source: Jabłoński and Malczewski 2014, Posobkiewicz 2015, Kryska 2016

The poisonings during this period may have been largely caused by the product called “Mocarz” (English translation: ‘athlete’). It was suspected that the mass poisonings from Mocarz were connected to changes in its ingredients. According to the National Drug Institute of Warsaw, the active ingredient in Mocarz changed from JWH-203, JWH-081, JWH-019 in 2010, to UR-144 and 5F-AKB48 in 2014, and finally UR-144 and XLR-11 in 2015 (Information Center for Drugs and Drug Addiction, 2015). In 2015, a new synthetic cannabinoid called MDMB-CHMICA was detected in Mocarz. Several dozen fatal poisonings have been connected with this synthetic cannabinoid in Europe since 2014 (EMCDDA & Europol, 2016). One fatal poisoning has been confirmed in Poland (Adamowicz, 2016). Analysis of NPS poisonings from the first half of 2015 shows that the most-serious cases were related to PMA, PMMA, 25C-NBOMe, and 25I-NBOMe (Kabata, Schetz, Waldman, Wiergowski & Sein Anand, 2015). The increase in the number of poisonings related to NPS in recent years is probably the result of several factors including increasing toxicity of the compounds used in products, increasing number and availability of NPS products, and a growing number of NPS consumers.

## NPS in the United Kingdom

NPS has been a public health concern in the UK for a number of years (Stephenson & Richardson, 2014). A range of “herbal” or “legal” highs were sold from retail shops across the country, including from petrol stations (Hughes & Winstock, 2012). The open sale of these products was seen to give them an aura of legality and respectability, and create the impression that they were not dangerous (Hughes & Winstock, 2012; Stevens, Fortson, Measham & Sumnall, 2015). It was estimated that up to 335 “headshops” sold NPS products throughout the UK during this time (Stevens, et al., 2015).

Mephedrone emerged as a particularly popular legal high in the U.K. during the late-2000s, with large increases in use observed in 2009 and 2010, reflecting its easy availability from legal retail outlets and websites. At its height mephedrone was said to be the fourth most popular recreational drug behind cannabis, cocaine and ecstasy. The prevalence of mephedrone declined following its ban in 2010 (i.e. 1.3% in 2010-2011; 1% in 2011-2012 and 0.5% in 2012-2013 (Home Office, 2014)), but high levels of use have persisted among certain subgroups such as the LGBT community (Measham, Wood, Dargan & Moore, 2011; Wood, Measham & Dargan, 2012). The rate at which new NPS appeared on the UK market peaked at 16 compounds in 2010; before declining slightly to 13 new compounds in 2011 and 2012, and 11 in 2013 (Home Office, 2014; Stephenson & Richardson, 2014).

The ongoing issue of legal high products openly sold from retail outlets compelled the UK Government to take action. A 12-member government-appointed committee of drug policy experts, the NPS Review Expert Panel, was established to guide the technical discussion as to what should be done in regard to the NPS problem (Reuter & Pardo, 2016). The Panel’s main objective was to provide recommendations to the Home Office and other administrative and enforcement organisations in regard to the nature of the NPS phenomenon and investigate different options for regulating NPS, while reviewing current policy and legislative responses.

### *The UK Psychoactive Substances Bill 2016*

The Government’s response was to introduce the UK Psychoactive Substance Bill 2016 (UK-PSB), which imposed a ‘blanket’ ban on all psychoactive substances except those on a list of exempted substances, including alcohol, incense, e-cigarettes, tobacco, and food (Reuter & Pardo, 2016; Stanley, Mogford, Lawrence & Lawrie, 2016; Stevens, et al., 2015).

The PSB attracted considerable criticism from various sectors of society, ranging from LGBTQ activists concerned that the PSB would ban substances like popper (i.e. alkyl nitrites), to scientists that argued against the effectiveness of the blanket bans, to religious leaders who lobbied for substances like incense to be formally excluded from the Act (Evans-Brown & Sedefov, 2016; Reuter & Pardo, 2016). A critical letter signed by 40 prominent scientific and policy figures, including Colin Blakemore, Lord Ramsbotham and David Nutt, described the UK-PSB as “very poorly drafted, unethical in principle, unenforceable in practice, and likely to constitute a real danger to the health and well-being of our nation’s citizens” (Reuter & Pardo, 2016). Other critiques emerged from the Advisory Council on the Misuse of Drugs (ACMD), an independent expert body that advises the government on drug-related issues in the UK and is usually closely aligned to Home Office drug policy.

The central issue of concern raised by the ACMD was the “blanket ban” of the UK-PSB is based on a very broad definition of ‘psychoactivity’, that is “any substance capable of producing a psychoactive effect in a person who consumes it”. Such a loose definition includes any substance able to affect a person’s mental function or emotional state by stimulating the central nervous system, even in instances where the effect is minimal. This could include the use of flowers, perfumes and vaping, to name just a few. The UK-PSB potentially covers the use of any substance

that facilitates an alteration of consciousness. The legislation explicitly exempts alcohol, tobacco and medicines. It has been argued that the UK-PSB fails to link the definition of psychoactivity to harm, and therefore decisions to ban a substance are no longer based on scientific evidence of health risk. Furthermore, exemptions of alcohol and tobacco appear purely based on cultural and social tradition.

It is also not clear how the 'psychoactivity' of a substance will be scientifically established. Under the previous scheduling process, the assessment of the risk of a substance was carried out by the ACMD and based on evidence of harm of the drug in question. This proved to be challenging in the case of many NPS, as they were novel compounds with little or no scientific studies of their health risk. At present there are no biochemical tests to detect psychoactivity, leaving its determination to subjective human experience (ACMD 2015). As a result, judges will have limited or no evidence to guide decisions on the magnitude of penalties (Stevens, et al., 2015).

While the UK-PSB does not impose criminal penalties for personal use and possession, it does establish severe criminal penalties for individuals who import such substances for consumption. This could include the case of an individual buying from the Internet, acting alone or with a group of friends, making this 'a potential abuse in the law and misapplication of justice' (Reuter & Pardo, 2016).

### **NPS in New Zealand**

New Zealand had a particularly early experience of the NPS problem. In the early 2000s, the high price and poor quality of MDMA in New Zealand created a market for "legal" benzylpiperazine (BZP) "party pills" (Sheridan, Butler, Wilkins & Russell, 2007). At the time BZP was not scheduled at the domestic or international level. The response of the New Zealand authorities in 2004 was to call for further research of the health risks of BZP, and to explore the possibility that low risk psychoactive products like BZP could remain on the legal market if they were subject to stricter regulatory controls (EACD, 2004). During the three years in which the commissioned research was completed, the BZP market grew significantly (Wilkins, Girling & Sweetsur, 2007; Wilkins & Sweetsur, 2010).

BZP was eventually prohibited in 2008 following a reassessment of its health risks (EACD, 2006; Wilkins, Sweetsur & Girling, 2008). While this drastically reduced its use and availability, producers immediately switched to a range of non-BZP products, including the newly emerging synthetic cannabinoids. The apparent ineffectiveness of the traditional scheduling process to control the NPS market led to a search for a more sustainable long term solution.

The New Zealand Law Commission was tasked with providing such a solution and, following an in-depth review, recommended the development of a pre-market approval regulatory regime, similar to the regime commonly used for medicines (New Zealand Law Commission, 2011). This approach effectively "reverses the onus of proof" from the government having to show products already on the market are unsafe, to manufacturers having to prove products are safe in advance of legal sale (New Zealand Law Commission, 2011). The resulting *Psychoactive Substances Act* (NZ-PSA) established this new approach and was passed nearly unanimously by the New Zealand Parliament (i.e. 119 voting in favour of the PSA to 1 voting against) in mid-July 2013.

#### *The Psychoactive Substances Act 2013*

Under the NZ-PSA, psychoactive products which can be shown with toxicology and clinical trial data to pose a "low risk" of harm will be approved for legal manufacture and sale, subject to a range of regulatory standards (New Zealand Parliament, 2013). Product sponsors are responsible for conducting and paying for the required product testing, and must also pay an application fee of \$180,000 (\$NZ) per product (Ministry of Health, 2012). Alcohol, tobacco,

medicines and dietary supplements are all exempt from the NZ-PSA as they have their own legislation (Rychert & Wilkins, 2016). Compounds which are already scheduled under the *Misuse of Drugs Act* are also not eligible to be assessed under the NZ-PSA (Rychert & Wilkins, 2016). Approved products are sold subject to a range of generic retail restrictions including a minimum purchase age of 18 years, and no sales from convenience stores or those that sell alcohol or automobile fuels (New Zealand Parliament, 2013). The advertising of approved NPS products is limited to the “point-of-sale” only (i.e. no advertising in television, radio, or newspapers) (New Zealand Parliament, 2013). The PSA specifically prohibits sellers from advertising an approved product as “safe”.

Approved products are permitted to be advertised and sold from websites specifically established for that purpose, but not from the wider internet (New Zealand Parliament, 2013). The PSA requires license holders to report adverse effects from approved products, and the regulator has the power to withdraw a product based on these reports (New Zealand Parliament, 2013). The PSA also established the Psychoactive Substances Regulatory Authority (PSRA) to administer the NZ-PSA and to develop further regulation for the new regime (New Zealand Parliament, 2013).

#### *The Interim Psychoactive Substances Act regime*

At the time of enactment of the NZ-PSA, key parts of the regulatory framework were yet to be developed, including the product testing standards (Wilkins, 2014a). A transitional interim regime was therefore established while this regulation was developed (Wilkins, 2014a).

The enactment of the PSA did bring about a number of immediate changes to the legal high sector (New Zealand Parliament, 2013; Wilkins, 2014a). All NPS products, and those involved in their manufacture, distribution and retail sale, were now required to have interim licenses, and the sale of licensed products was subject to the retail and advertisement restrictions detailed in the PSA (Wilkins, 2014a). All unlicensed products were prohibited by default.

Manufacturers were permitted to apply for an interim product license for existing untested products, if the products had been on the market for at least three months prior to the passage of the PSA (Ministry of Health, 2013a, 2014; Wilkins et al., 2013) and the product had not received any official reports of adverse events during that time. Applicants were required to pay an interim license fee (i.e. \$10,000 per product license and \$500 for a retail license) (Ministry of Health, 2013a; Wilkins, 2014a). The interim licensing requirements reduced the number of NPS products on the market from 200 to 46, and reduced the number of retail outlets from 3,000–4,000 largely convenience stores to 156 licensed specialty ones (Wilkins, 2014b).

The interim PSA regime proved to be controversial. There were ongoing reports of adverse effects from products and growing public concern about the level of anti-social behavior around retail outlets, including intoxication, intimidation and begging (Wilkins, 2014c). The legal high Industry argued much of social nuisance around retail outlets was created by the reduction in the number of retail outlets which greatly increased the number of customers patronizing each store (Rychert & Wilkins, 2016a). These problems were widely reported by the media and community protests were organised against local retail outlets. A much broader protest movement emerged against the PSA when it became clear that animals were to be used to test the safety of products (Ministry of Health, 2014; Rychert & Wilkins, 2015). The Government responded by bringing the interim PSA regime to an abrupt end. It withdrew all interim licenses in May 2014, effectively making all psychoactive products illegal.

#### *The future of the Psychoactive Substances Act regime*

While the interim regime was ended, the original NZ-PSA legislation remains in legal force, and the PSRA continued to develop the regulatory framework required for the full operational of the intended regime. In November 2014, the PSRA announced they were now ready to receive

product applications (OPSRA, 2014). As of December 2016, they have yet to receive any product applications. The PSRA believe the ban on animal testing of products has created a significant barrier to achieving a successful product approval (OPSRA, 2014). While there appear to be viable strategies to overcome this impasse, it is unclear whether there is sufficient political will to continue with the regime (Rychert & Wilkins, 2015).

## Overall Conclusions

The four country case studies of the response to NPS presented in this chapter underline a number of commonalities in what is now commonly referred to as the “NPS problem”. The initial response was to attempt to prohibit individual NPS compounds using traditional scheduling processes, often requiring final legislative approval. These traditional processes proved to be problematic due to the slowness of the administrative and legislative processes, and the ability of manufacturers to quickly replace a newly controlled compound with an entirely new unrestricted one. The ease with which new compounds with slightly different chemical structures from controlled ones could be produced meant the process of scheduling individual compounds became largely futile. In Poland it was observed that a chemist could develop a structural analogue to a banned substance within several weeks, while the legal procedure of extending the list of controlled substances took three to nine months (Hughes & Blidaru, 2009). The ineffectiveness of traditional scheduling of individual compounds led to the adoption of “catch all” definitions of psychoactive products, which allowed the comprehensive prohibition of all current and future psychoactive products regardless of their chemical structure.

There was some evidence from Poland and Ireland that these measures may have reduced the use and harms from NPS for a number of months. In Poland, lower levels of NPS poisonings were recorded for over two years following the closure of all headshops and adoption of a new legislation. In New Zealand too, the prohibition of BZP significantly reduced BZP use and suppressed the wider legal high market for 18 months or so (Wilkins and Sweetsur, 2013, Wilkins et al., 2014).

However, users and sellers adapted to these new comprehensive controls over time by accessing products from websites based in other countries, and from the black market. While this adaptation to new enforcement pressure will not surprise those familiar with the workings of illegal drug markets, a more disturbing unintended side effect appeared to be that the replacement compounds tended to be more potent and toxic than the original ones. This escalation in toxicity has been previously noted during the early emergence of synthetic cannabinoids. There appears to be a plausible explanation for this unintended side effect of control, in that even clandestine manufacturers tend to start with the most stable compounds as they encourage returning customers, only turning to more volatile compounds as the former are banned. A related observation is that much of the focus of the policy response to NPS to date has been on restoring the power of prohibition as opposed to addressing the health issues of NPS use, such as by providing clear information about health risks and improved access to drug treatment and other health services.

The United Kingdom’s Psychoactive Substances Act raises important issues about the extent to which “catch all” bans based solely on psychoactive *effects* undermine the central rationale of drug prohibition. The previous rationale for prohibiting a drug was supposedly that carefully accumulated scientific evidence of harm indicated the substance posed an unacceptable high risk to users and wider public. Prohibition based merely on psychoactive effect eschews any need to assess health harms related to a drug and more closely resembles prohibition based on moral judgment. This suspicion is enhanced by the fact that a number of traditional psychoactive

products with known health risks, such as tobacco and alcohol, are routinely exempt from “catch all” legislation, seemingly only because their use is already normalised and commercialised in society.

The pre-market approval regime for NPS developed in New Zealand also emerged out of frustration with the ineffectiveness of the traditional individual scheduling process, but in contrast to the prohibition approaches pursued in other countries, sought to develop a long term sustainable solution based on establishing a regulated market for “low risk” NPS products (Wilkins et al., 2013). The central idea is that this regulated market for low risk NPS products will draw demand away from the grey market of untested products, while also providing consumers with safer products and reliable information about potency, ingredients and health risks (Wilkins, 2014a). This regulated market approach offers a number of key advantages over traditional prohibition approaches, including requiring manufacturers to prove their products are “low risk” in advance of legal sale, improving the safety of products legally available, and providing more nuanced regulatory control over the market, for example age of purchase limits, licensing of sellers and health warnings on packaging (Wilkins, 2014a). However, there are clearly risks with developing a government sanctioned legal market for psychoactive products as it may encourage greater use of them with related adverse health consequences (Wilkins, 2014a). It is also unknown whether this regulated legal market for low risk NPS will reduce or increase the use of alcohol, tobacco and illegal drugs with related health burdens (Wilkins, 2014a). The challenge for governments interested in regulated markets for NPS is to develop effective regulation of these new sectors (Wilkins, 2014a). Unfortunately, it is by no means clear from the recent legal regimes for cannabis that the hard lessons from the regulation of alcohol and tobacco harms are automatically being applied to new legal markets for psychoactive products (Ghosh et al., 2016). A fairly ironic postscript to the failed interim NZ-PSA regime is as all product licenses have now been withdrawn, and all unlicensed psychoactive products are illegal by default under the regime, New Zealand essentially now has a blanket ban of all psychoactive products very similar to the ones that have been in operation in the Republic of Ireland, Poland and the U.K. (Wilkins & Rychert, 2016).

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