Synthetic Cannabinoid Use in New Zealand: Assessing the harms

A report to The STAR Trust

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Executive Summary

A brief review of international literature was followed by more detailed analysis of peer-reviewed New Zealand data on synthetic cannabinoid harms. This material was combined with non-peer-reviewed New Zealand quantitative and qualitative data including those sourced from: regular and on-going public health surveillance, treatment sector raw data, Government and industry reports, and media articles. Limited formal and informal correspondence with individuals associated with some of the above sources supplemented formal data assessment.

A range of harms reflected in negative symptomatology, consistent with those reported by international and New Zealand researchers, and Government (specifically Ministry of Health, 2013c2-3), was identified:

- symptoms including tachycardia, agitation, vomiting, sweating, hypertension, fainting, hypotension, confusion, cramp, rhabdomyolysis, and breathlessness;
- while some symptoms are shared with raw cannabis, others appear UNIQUE to synthetics, or at the least are exaggerated in synthetics;
- some negative symptoms resulted from limited and acute exposure;
- it is likely that a significant proportion of the negative events reported up to the end of 2013 are associated with now prohibited products;
- following the passing July of the Psychoactive Substances Act 2013 (hereafter PSA 2013), data suggest reductions in incidence and prevalence of harms reported by some sources.

Analysis revealed limited and piecemeal collection and reporting of New Zealand data. Prevalence statistics of negative events also appear to have been influenced by media coverage, with some media reports potentially exaggerating the incidence or magnitude of events.

The discussion of harms emphasised the dynamism and nascency of the New Zealand market for associated products and the management of harms, including public health surveillance, and legislative and industry response to these, such as risk assessment and quality control of products.

In summary, the increasing sophistication and efficacy of risk assessment processes and the concomitant improved safety of products is supported by evidence of reduced numbers of retail outlets and product lines, and lower prevalence of negative events. Gaps identified suggested a need for greater communication between The Authority and local councils, e.g. in relation to the development and deployment of LAPPs. Increased monitoring of internet sales—to reduce underage access—and the possibility of minimum pricing—given the considerable overlap between the synthetic and raw cannabis market—were discussed as responses to further reduce harm.
Recommendations noted:

- the need for industry to acknowledge the harms associated with its products but to emphasise continuing reductions in prevalence and incidence;

- industry should highlight its compliance with legislation’s requirement that products evince only a low level of harm and that this is recognised by officials to be less than that associated with alcohol;

- to reflect their commitment to harm reduction, The STAR Trust and members of PITA are strongly encouraged to include health advice for consumers on their websites. Links should be consistent across organisations and reflect professional best practice in identifying and providing information, preferably with links to independent resources. Ideally retail staff would receive practical harm reduction training to identify and engage with customers having problems. Competency should be subject to PITA audit;

- the industry is encouraged to continue networking with all willing non-stakeholder entities, e.g. local bodies and the health sector, especially treatment services. Transparency and facilitation should be emphasised;

- increased monitoring of internet sales, particularly regarding under age consumers, and minimum pricing (to avoid increased consumption) are indicated. Price should be comparable with raw cannabis, i.e. approximately $12 / gram;

- appropriate research, including research partnerships, should continue to be supported. Emphasis should be on quality and tangible outputs, including relevant peer reviewed publications;

- consideration should be given to exploring the development of non-recreational drugs having relevance to current NPS product lines, e.g. products potentially attenuating withdrawal symptoms of current New Zealand products or those existing elsewhere. Re-visiting the inclusion of CBD-type analogues in extant products should be considered.
1 Introduction

The primary aim of this report, commissioned by The STAR Trust in October 2013,\(^1\) is to critically assess harms experienced in New Zealand, associated with the consumption of synthetic cannabinoids. These are a subset of the class of recreational drugs known globally as New Psychoactive Substances (NPS) (UNODC, 2013) and also as cannabimimetics (Zawilska & Wojcieszak, 2013). The analysis of harms will in part be achieved through a brief comparison of the former with harms caused by other legal drugs, specifically alcohol and raw cannabis.

Part 1. Synthetic Cannabinoids

This section of the report considers international literature before focusing on New Zealand data. The latter include the small number of peer reviewed articles extant at the time of writing, government reports and raw data from the treatment, drug monitoring and enforcement sectors. Industry data and media reports complete the analysis.

1.1 Background

Zawilska and Wojcieszak (2013:1) describe synthetic cannabinoids as a relatively new type of designer psychoactive drug that has latterly appeared on the recreational drug market. These ‘synthetic cannabimimetics’ are cannabinoid receptor agonists mimicking the effects of cannabis. Barratt et al (2013) note their structural dissimilarity to Δ-9-tetrahydrocannabinol (THC), cannabis’ principal psychoactive compound, but that they act on the body’s endocannabinoid system in the brain, primarily on the CB1 receptor. Hudson and Ramsey (2011) have classified these into eight groups including: classical cannabinoids (e.g. Nabilone), cyclohexylphenols or non-classical cannabinoids (e.g. CP 47,497), benzoylindoles (e.g. AM-694), phenylacetylindoles (e.g. JWH-250), naphthoylindoles (e.g. JWH-018), naphthylmethylindoles (e.g. JWH-185), naphthoylpyrroles (e.g. JWH-369) and naphthylmethylenindenes (e.g. JWH-176). Seely and colleagues (2012) suggest these diverse categories of synthetic cannabinoids may act as full, partial and inverse agonists at the CB1 receptors, as neutral antagonists and that some also show affinity to the CB2 receptors.

Synthetic cannabinoids’ recent arrival on the global drug scene likewise figures in the European Monitoring Centre for Drugs and Drug Addiction’s current annual report (EMCDDA, 2012), where 49 new psychoactive drugs were detected in 2011. In 2012 a further 73 NPS were detected, of which 30 were synthetic cannabinoids (EMCDDA, 2013). These trends are discussed in the United Nations Office on Drugs and Crime’s (UNODC) latest World Drug Report. That document notes difficulties in controlling

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\(^1\) http://thestartrust.org/background
the “dynamic, fast-mutating” market and product lines, suggesting the phenomenon of NPS “can have deadly consequences” for users (UNODC, 2013:ix).

While the present report will demonstrate there is clear evidence of harm associated with the consumption of synthetic cannabinoids, fatalities resulting from their use are extremely rare. For example, in their wide-ranging review Zawilska and Wojcieszak (2013:12) comment that they are aware of only one fatality categorically associated with the consumption of synthetic cannabinoids since these first appeared on the European recreational drug market in 2004 (see Patton et al., 2013). There are, nonetheless, further unconfirmed reports emanating from print and other media. For example in Perth, Western Australia, in 2011 a heart attack death was attributed to Kronic Black Label by local media (Phillips, 2011). Indirect attributions are also made, for example, in the US K2 was blamed for the 2010 suicide of one user (Gay, 2010). More recently the New Zealand Herald (May 9, 2013) reported the death of a male, attributed by a Japanese toxicological report to acute poisoning from the synthetic cannabinoid MAM-2201. Nonetheless, that article also included comments from New Zealand toxicologist Leo Schep, cautioning against interpreting the report as conclusive evidence of cause of death.

It is unsurprising, therefore, to see mainstream media more frequently presenting extreme consequences of novel drug use, compared with reports from formal peer reviewed and rigorous official analyses. Forsyth (2001) has noted this previously with regard to the media’s selective reporting of Scottish Ecstasy deaths. And indeed this is the case for synthetic cannabinoids, where an Australian analysis makes the case for a moral panic created through selective reporting of negative events associated with the brand Kronic (Bright et al., 2013).

Thus in attempting to gain a clear picture of the actual harms of synthetic cannabinoids experienced by New Zealand consumers and their affiliates, it is necessary to separate and critically assess various strands of data. Consequently the present report reviews a range of data streams including: peer reviewed literature, with an emphasis on New Zealand data; statistics and related data such as those from Massey University’s Illicit Drugs Monitoring System (IDMS) and the NZ Arrestee Drug Use Monitoring (NZ-ADUM) data sets; National Poisons Centre (NPC) statistics; ED and hospital presentations and admissions data, and related DHB information; Alcohol and Other Drug Helpline call data; Ministry of Health data and reports; and, reports from other government agencies, e.g. Treasury and Justice. These sources of formally constituted information (i.e. primarily peer reviewed) are supplemented with ‘grey’ literature, e.g. media articles and industry reports.

The report also draws on informal interviews and correspondence with key individuals, with these being referred to in text as ‘personal communication’, with named individuals where appropriate.

1.2 International literature

A substantial review of international literature relevant to synthetic cannabinoid use and associated harms is beyond the scope of the present report. For these the reader is directed to recent examples including Zawilska and Wojcieszak (2013), and the
ECMDDA’s 2013 brief summary and its companion on-line resource.\textsuperscript{2} It is appropriate, however, to locate the New Zealand experience of this type of NPS within the broader global environment. This will facilitate the contextualising of the New Zealand situation across various dimensions including prevalence, availability, legislation and relative harm.

1.2.1 Prevalence

Drug use data are typically compiled on the basis of prevalence at the national level and reported in that context domestically and internationally. This is the case in New Zealand as elsewhere with, for example, New Zealand reporting to the United Nations annually and that organisation’s Office on Drugs and Crime (UNODC) then providing a comparative global picture of legal and illegal drug use (e.g. UNODC, 2013). In summary the latter notes the following international trends with regard to synthetic cannabinoids:

- the burgeoning market for NPS (e.g. almost 5% of European youth aged 15-24), this market characterised by lack of legislative control and mutability of product lines, e.g. from 166 substances in 2009 to 251 in 2012 (\textit{ibid}:ix-xii);
- lack of research into adverse effects of various substances (\textit{op. cit});
- use per product declining with introduction of legislative controls (\textit{ibid}:xi);
- at 2012 synthetic cannabinoids made up 23% of NPS (\textit{ibid}:xii);
- significant use by younger people (e.g. aged 15-24) (\textit{op. cit.});
- significant role of the internet for information and production of NPS, despite European data suggesting only 7% of above consumers using the internet to actually purchase their drugs (\textit{op. cit});

The EMCDDA (2013:1) suggests that synthetic cannabinoids, i.e. those mimicking the effects of \(\Delta^9\)-THC, the main psychoactive chemical found in cannabis, to variable degrees, have likely been available since 2006, though a previous publication notes it may have been as early as 2004 (EMCDDA, 2009). Quoting ‘Eurobarometer’ data from 2011, UNODC (2013:13) claims that almost 75% of EU users were concentrated in five countries: UK (23%), Poland, (17%), France (14%), Germany (12%) and Spain (8%). UNODC’s report should, however, be read carefully as the figures quoted represent each country’s proportion of all synthetic cannabinoid users in the EU, who have ever tried these substances. The actual \textit{lifetime prevalence} figures for use per country for the EU are considerably more modest, with the EMCDDA (2013:3) reporting the following: UK, 0.1% (adults 18-64); Spain, 1.1% of a sample of 25,000 (14-18 year olds); Frankfurt, Germany, 9% for ‘herbal products and Spice’ (15-19 year olds, i.e. synthetic cannabinoids not specified). In casting a broader net, these authors reference an internet survey, the ‘Mixmag Study’ (2012) (aka \textit{The Global

\textsuperscript{2} Available at emcdda.europa.eu/topics/pods/synthetic-cannabinoids
Drug Survey) which reported on use by a non-probabilistic sample of EU internet users and clubbers, indicating levels of 10.3% lifetime and 2.2% last year use.\(^3\)

Overall, data from the Global Drug Survey (Winstock & Barratt, 2013a & 2013b) claim global lifetime prevalence for synthetic cannabinoids of 17% amongst those participating (n=14,966) and 6.5% use last year. The high level of use reported by these authors should also be viewed with caution as their data were gathered purposively via the internet and therefore are not representative, either of the general population or of drug users specifically, limitations acknowledged by the authors (Winstock & Barratt, 2013b:110).

Nonetheless the study is useful for elucidating characteristics of synthetic cannabinoid use. For example, of recent users of synthetics over the preceding 12 months (n=980), 99% reported ever using raw cannabis, with 93% reporting a preference for it over synthetics due to the latter being more associated with negative effects (e.g. hangover and paranoia). These authors (Winstock & Barratt, 2013a) noted also the relatively high proportion of last year users reporting seeking medical attention following use (2.4%). Those seeking help were significantly younger than those who did not (median age 20 vs 23; p=0.004). Overall raw cannabis was preferred over synthetics’ less desirable effect profile.

UNODC’S 2012 data indicate that the US identified the largest number of NPS (158), more than twice that noted in Europe (73) during the same time period. Of NPS identified in the US in 2012, 51 were synthetic cannabinoids, up from 2 in 2009. UNODC (2013:xiii) suggests the principal user group in the US is students, with use for this group being more than twice that of European students. A first time survey of high school students in 2011 reported last year use of 11.4% (ibid, 2013:12). Data from northern neighbour Canada indicate a relatively high level of use, with that country identifying 59 NPS in 2012, of which 16 were synthetic cannabinoids.

Further evidence of the NPS market’s growth is indicated by European data (EMCDDA, 2013) reporting increasing numbers of synthetic cannabinoids from year to year, with 9 reported in 2009, 11 in 2010, 23 in 2011 and 30 in 2012. By May 2013 there were 84 synthetic cannabinoids notified to the EMCDDA, making these the largest group of psychoactive chemicals monitored by the EU’s early warning system (EWS).

New Zealand’s key role in the NPS market is specifically noted by UNODC (2013), with 44 NPS identified in Oceania in 2012, accounting for 25% of all such substances identified globally.

Overall, 70 (88%) of countries contributing data to the UN’s most recent annual drug report recorded a market for NPS, with the highest number of countries coming from the blocks of the EU (37) and Asia (19). Synthetic cannabinoids (66%) dominated this new market between 2008-12 (UNODC, 2013:67), with some of the highest prevalence noted in Oceania, where the report reiterates New Zealand as being a key player (ibid, 2013:91). For the latter, this was built on the back of the market for Benzylpiperazine (BZP) which, when scheduled as a class ‘C’ drug in 2008, saw a significant decline in the prevalence of ‘legal highs’ in New Zealand between the period 2005-10, compared with increases elsewhere around the globe. Nonetheless,

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\(^3\) http://globaldrugsurvey.com/
between 2006-2012 most Internet searches for BZP were conducted in New Zealand (ibid, 2013:99). As the UNODC report notes, this reduction in use represents an example of the efficacy of legislation reducing harms through controlling a substance identified as problematic (ibid, 2013:98).

Even so, despite the growing awareness of a range of issues associated with synthetic cannabinoids, including the potential efficacy of targeted regulation, significant gaps remain in available data.

One attempt at a broad analysis of synthetic use is an Australian study (Barratt et al., 2013), with an online questionnaire being administered to a purposive sample of 316 synthetic cannabinoid users. Ninety-six percent of the sample (77% male, median age 27) reported previously having used cannabis. Their reasons for synthetic use included: curiosity (50%), legality (39%), availability (23%), recreational effects (20%), medicinal effects (9%), non-detection in standard drug screening assays (8%) and to aid the reduction or cessation of cannabis use (5%). Users reported buying a median of 3 grams per purchase and paying a median of AUD$60. Interestingly 215 of the sample (68%) and more frequently those aged 18-25, reported at least one negative side effect during their last session of use. These included: decreased motor coordination (39%), fast or irregular heartbeat (33%), dissociation (22%), dizziness (20%), paranoia (18%) and psychosis (4%). Only 4 of the 215 (2%) reported seeking help.

The small proportion of the above sample actively seeking help for negative events associated with synthetic cannabinoid use is disproportionately represented through the media, according to a second Australian study. In this analysis examining media response to harms associated with synthetic cannabinoids, Bright and colleagues (2013) used Google’s search engine applications to produce time-trend graphs tracking the volume of online media stories published about synthetics and particularly the brand ‘Kronic’ during 2011, along with the number of searches representing these terms. These authors noted the strong association between media stories and the number of searches for published terms and brands, as well as dominant discourses or narrative themes within the media articles, constructing synthetic cannabis as pathogenic. The authors described the result as a ‘moral panic’ and reported how Australian state and federal governments reacted to this by banning individual synthetic cannabinoid agonists. This in turn led to manufacturers releasing new synthetic blends claiming to contain novel unscheduled chemicals.

The above scenario reflects similar trends across the Tasman in New Zealand. While Bright and colleagues (2013) conclude that well intentioned policy responses to moral panics can have unintended consequences such as raising awareness of banned products and stimulating the introduction of new ones of unknown potential harm, the precise nature of new regulations is also of significance. Section 1.3 (below) discusses the New Zealand situation by comparison, examining its unique landscape, and policy and other responses to this. Prior to this, however, a more detailed description of specific harms experienced by synthetic cannabinoid consumers is useful to place policy and other sector responses in context.
1.2.2 Harms reported internationally

Increasingly, data from international studies have indicated the potential for a range of harms associated with the recreational use of synthetic cannabinoids. Bright and Barratt (2013) summarise these as follows:

- **Cognitive**: Confusion, disorganised thought, memory problems, difficulty thinking clearly;
- **Behavioural**: agitation, restlessness, aggression;
- **Mood/affect**: anxiety, irritability, inappropriate laughter;
- **Sensory/perceptual**: paranoia, perception distortions, delusions, hallucinations, psychosis;
- **Physical**: tachycardia, hypertension, nausea, vomiting, tremors, numbness, tingling, lightheadedness, seizures.

These authors also specifically mention reports of severe dependence/withdrawal symptoms. The latter have likewise been noted in New Zealand and are discussed in greater detail below. In an early international example, Zimmerman and colleagues (2009) described a single case of dependence on a German synthetic product containing JWH-018, ‘Spice Gold’. In that study a 20 year-old male who had consumed up to 3 grams of the product daily for 8 months, was admitted to hospital following abstinence at 4-7 days, with severe withdrawal symptoms. These included: inner unrest, drug craving, nocturnal nightmares, profuse sweating, nausea, tremor, and headache; blood pressure was elevated for two days, with a maximal value of 180/90 mm Hg accompanied by a heart rate of 125/min.

Other historic reports of negative reactions to synthetics include: acute exacerbation of cannabis-induced psychosis, described in Germany (Muller et al., 2010) and, in the US, severe agitation (Schneir et al., 2011); and seizure, unconsciousness, tachycardia and paranoia (3 separate cases) (Simmons et al., 2011) following the use of ‘Spice’.

A more recent study has added acute kidney injury (AKI) to this list of negative outcomes from the recreational use of synthetics. In this instance Murphy and colleagues (2013) reported on 16 cases of AKI across six US states. These authors noted that no specific synthetic cannabinoid product was implicated in all cases but that a fluorinated SC previously unreported in synthetic cannabis products—methanone (1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl), also known as XLR-11, was identified in four of five product samples and four of six patients' clinical specimens. Outcomes reported included nine patients having renal ultrasounds showing increased renal cortical echogenicity and six patients having acute tubular injury on renal biopsy. Kidney function subsequently returned to normal in most patients. Five patients, however, required hemodialysis and four received corticosteroids.

As discussed earlier, Zawilska & Wojcieszak’s 2013 article provides a useful review of recent evidence, which, in combination with Bright and Barratt’s (2013) analysis may be summarised as follows:

- These relatively new products, available since at least 2004, have been implicated in negative clinical events for consumers since at least 2009;
• A range of negative psychological and physical symptoms have been identified, with confusion, agitation, anxiety, paranoia, tachycardia, vomiting and tremors being most frequently reported internationally;

• More serious events include seizures, psychosis and acute kidney injury;

• Evidence of dependence has been reported (e.g. Zimmerman et al., 2009), with the suggestion that withdrawal effects may also be severe;

• While deaths have been attributed to synthetic cannabinoid use, those that are verifiable are reportedly very rare. For example Zawilska & Wojcieszak’s (2013:12) comment they are aware of only one;

• Nonetheless, despite the seemingly relatively frequent negative events experienced by consumers, many continue their use and relatively few appear to seek formal acute treatment. Thus, although 68% of an Australian sample (Barratt et al., 2013) identified at least one negative side effect during their most recent session, only 2% reported they had sought help.

1.3 Synthetic cannabinoid use in New Zealand

This section considers synthetic cannabinoid availability and prevalence in New Zealand, a range of data on harms, and government as well as other-sector information and responses to the phenomena of use. Data are derived from on-going surveys, such as those regularly undertaken by Massey University’s SHORE (e.g. IDMS and NZ-ADUM); Ministry of Health, DHBs and treatment sector organisations, and the police. Media articles and industry data are also incorporated.

1.3.1 Relevance of ‘raw’ cannabis to the synthetic cannabis market

With international data reporting a high proportion of synthetic cannabis consumers have previously used raw cannabis (Barratt et al., 2013; Zawilska & Wojcieszak, 2013), it seems likely there will be associations between the markets for these two products, including patterns of, and reasons for use, as well as demographic similarities between the two groups of consumers. Understanding the significance of cannabis use in New Zealand is therefore important.

As is the case internationally (UNODC, 2013), raw cannabis has consistently remained the most commonly used illegal drug in New Zealand. Wilkins and colleagues (2007) note a decline in cannabis use by New Zealanders between 2003 and 2006 for those aged 13-45 for lifetime use (51% vs. 42% respectively) and for use the previous year (20% vs. 17%). However, the most recently completed government survey of 6784 New Zealanders aged 16-64 (Ministry of Health, 2010) reports that in

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this age group, 45% reported lifetime use and 15% use in the previous year, suggesting prevalence may be relatively stable. Moreover, it is generally accepted that in surveys of illegal drug takers, respondents typically under-report, with the figure of at least 5% commonly suggested (Noller, 2008).

The Ministry’s report (2010) notes that for age, patterns of cannabis use are similar to those for other drugs, with a skew towards youth. In New Zealand lifetime consumption peaks for those aged 25-34 years with approximately 60% reporting use. In this age group males (51%) are more likely to have used than females (47%). For ethnicity in this age group, Māori (63%) are significantly more likely to report lifetime use than European New Zealanders (49%), with Pacific peoples reporting the least (37%).

Socioeconomic status appears to have no significant impact on the likelihood of reporting lifetime use (Ministry of Health, 2010).

Having greater relevance to wellbeing are data describing cannabis use over the previous twelve months. Of the 15% reporting this in the Ministry of Health (2010) sample, men (21%) were significantly more likely to have used during the preceding year than women (14%), with past-year use peaking for them in the age group 18-24, and for women in the ages 16-17 and 18-24. Again Māori (26%) were more likely than New Zealand Europeans (15%) to have used during the previous twelve months. Unlike with lifetime use, however, males living in socioeconomically deprived neighbourhoods were significantly more likely to have used in the previous twelve months than those less deprived (p<0.05). For women socioeconomic status did not significantly impact on use in the previous year (Ministry of Health, 2010).

A final important statistic from the Ministry of Health (2010) survey concerns age at first use, which was significantly more likely (p<0.05) to be at 21 years or later for women than for men. While both Māori and non-Māori were most likely to have commenced use of cannabis between ages 15-17, Māori were significantly more likely than non-Māori to have tried cannabis at 14 years or younger.

1.3.2 Availability and prevalence of synthetic cannabis

If one accepts general similarities with Australian cannabis users and their patterns of synthetic use (e.g. Barratt et al., 2013), New Zealand use of raw cannabis should similarly imply a ready market for synthetic cannabis. As already noted, therefore, cannabis data become of significant interest where synthetic cannabinoiids are concerned.

Earlier discussion referenced New Zealand’s high level of synthetic cannabinoid use relative to other nations, as well as the extent to which the preexisting BZP market, established in the early 2000’s, potentially prepared the ground for the rapid establishment of a market for this new class of recreational drugs. Notwithstanding the already established BZP market, it should therefore be appreciated that the popularity of cannabis amongst New Zealanders, suggested by the above data, no doubt contributes considerable impetus to local enthusiasm for synthetic cannabinoid products.
Regrettably, however, as the Ministry of Health has not published a detailed drug use survey since 2008 (e.g. Ministry of Health, 2010), there are only limited formally compiled data on synthetic cannabinoid prevalence, all of which might best be described as proxy measures. Data from the latest survey are due in mid-2014.

One source of the latter is the Illicit Drug Monitoring System (IDMS) survey, regularly undertaken by Massey University’s SHORE centre. This survey assesses recent drug use trends by a cohort of what it refers to as ‘frequent drug users’ of certain drugs who are typically also polydrug users, i.e. they typically use other drugs, not infrequently simultaneously. In reporting data to 2011 (Wilkins et al., 2012) they survey described drug use patterns from 372 individuals (161 frequent ecstasy users [69% male, mean age 22], 113 frequent methamphetamine users [78% male, mean age 32], and 98 frequent injecting drug users [62% male, mean age 39]).

The IDMS commenced collecting data on “synthetic cannabis” in 2010, with each of the three drug-type user groups reporting increases in use from 2010 to 2011. Between these two years ecstasy users increased synthetic cannabis use from 36% to 70%; methamphetamine users from 22% to 52% and injecting drug users from 14% to 22%.

Overall, IDMS data (Wilkins et al., 2012) suggest that synthetic cannabis products e.g. Kronic and Spice,5 accounted for the greatest proportion of the new drug types used by respondents. Thus, for ecstasy users, 30% reported first using synthetic cannabis in 2011, with first time use rates in that year higher for methamphetamine users (36%) and injecting drug users (34%). The survey’s most recent iteration showed this first time use declining in 2012 for Ecstasy users (11%) and methamphetamine users (29%) but an increase for injecting drug users (48%) (Wilkins et al., 2013:65).

The IDMS also reports on respondents’ uptake of drug treatment services. While ecstasy users claimed minimal drug treatment (lifetime 9%, current 3%), methamphetamine users (lifetime 38%, current 17%) and IDU (69%, current 35%) were far more likely to have had or currently be receiving drug treatment. Of those currently receiving treatment, aside from their drug of choice (e.g. ecstasy for ‘frequent ecstasy users’), the drugs users most commonly received treatment for, were alcohol (methamphetamine users 43%, ecstasy users 20%) and benzodiazepines (IDU 16%). Despite the high levels of reported synthetic cannabis use by IDMS respondents, none of those surveyed reported receiving drug treatment for synthetic cannabis.

Arrestees are a second ‘sentinel’ group whose drug use is potentially able to provide data on drug prevalence and specifically emerging drug use trends. Along with their IDMS reports, Massey University’s SHORE centre, in conjunction with the New Zealand police, also regularly surveys individuals at the time of their arrest. This

5 Commencing in the early phase of research into synthetic cannabinoid products, there appears to have been a practise for authors to genericise products as ‘Kronic’ or ‘Spice’, whether in fact these were the actual names of specific products. This has led to a collapsing of product names and also a tendency for particularly the negative characteristics of those specific products, to be attributed to all synthetic cannabinoid products. This point is taken up in the discussion. See for example Fattore, L., & Fratta, W. (2011). Beyond THC: the new generation of cannabinoid designer drugs. *Frontiers in behavioral neuroscience*, 5.
The project is known as NZ-ADUM (New Zealand Arrestee Drug Use Monitoring). The survey’s most recent iteration (Wilkins et al., 2012) reported data from interviews with 828 police detainees in five New Zealand centres over 2011, four in the North Island and Christchurch in the south.

As with the preceding discussion of IDMS data, emerging drug trends are of particular relevance to the NZ-ADUM. Likewise with the IDMS, respondents in the NZ-ADUM survey reported a significant recent uptake of synthetic cannabinoid drugs. Therefore, despite some of the five surveyed centres showing individually relatively high levels of the novel use of ecstasy and methamphetamine, synthetic cannabinoids were most frequently reported as a new drug across sites collectively, by detainees (26%). This compares with the novel use of ecstasy (22%) and methamphetamine (12%). Perhaps of greater significance is the rapid increase in the popularity of synthetics, with no detainees from the surveyed sites reporting synthetics’ novel use in the preceding year (i.e. 2010). Christchurch Central (0% to 49%) and Auckland Central (0% to 20%) showed the greatest increases between 2010-11 (Wilkins et al., 2012:184).

Similarly, in discussing data for the Alcohol and Drug Helpline, the IDMS report noted no calls featuring synthetic cannabis for the years 2007-2011. During these years, alcohol dominated, with an increase from 63% to 70% between 2006/06 and 2010/11. Cannabis was the second most called about drug, effectively stable during these two periods, i.e. 15% to 16% respectively (Wilkins et al., 2012).

### 1.3.3 Synthetic cannabis harms in New Zealand

<table>
<thead>
<tr>
<th>Table 1: Alcohol Drug Helpline monthly call data for synthetic cannabis for the period January 2012 – December 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>SC as % of Alcohol Drug Helpline calls</td>
</tr>
<tr>
<td>Jan-12 0.20%</td>
</tr>
<tr>
<td>Feb-12 0.10%</td>
</tr>
<tr>
<td>Mar-12 0.70%</td>
</tr>
<tr>
<td>Apr-12 0.80%</td>
</tr>
<tr>
<td>May-12 0.30%</td>
</tr>
<tr>
<td>Jun-12 0.60%</td>
</tr>
<tr>
<td>Jul-12 0.90%</td>
</tr>
<tr>
<td>Aug-12 0.50%</td>
</tr>
<tr>
<td>Sep-12 1.50%</td>
</tr>
<tr>
<td>Oct-12 1.50%</td>
</tr>
<tr>
<td>Nov-12 3.00%</td>
</tr>
<tr>
<td>Dec-12 2.90%</td>
</tr>
<tr>
<td>Jan-13 3.00%</td>
</tr>
<tr>
<td>Feb-13 4.90%</td>
</tr>
<tr>
<td>Mar-13 7.90%</td>
</tr>
<tr>
<td>Apr-13 8.20%</td>
</tr>
<tr>
<td>May-13 8.20%</td>
</tr>
<tr>
<td>Jun-13 10.30%</td>
</tr>
<tr>
<td>Jul-13 10.10%</td>
</tr>
<tr>
<td>Aug-13 7.00%</td>
</tr>
<tr>
<td>Sep-13 4.30%</td>
</tr>
<tr>
<td>Oct-13 5.40%</td>
</tr>
<tr>
<td>Nov-13 5.80%</td>
</tr>
</tbody>
</table>

*Synthetic Cannabis – Kronic/Dream/Spice etc.*

As previously discussed, New Zealand data formally examining harms are limited and may be described as piecemeal. These consist of a small number of peer reviewed studies and commentaries, information collected in the course of health and medical sector surveillance (e.g. National Poisons Centre and the New Zealand Pharmacovigilance Centre – CARM) and government statistics. Other, less formally collected data, such as those from the Alcohol Drug Helpline, also provide a further proxy measure of these harms perceived by some consumers of synthetic cannabis products.

Compared to data from the IDMS, the Alcohol Drug Helpline’s more recent statistics (*Table 1*) indicate an increasing level of concern by consumers of synthetic cannabinoids calling that service, commencing in early 2012. These data show a steady rise in calls where the primary drug of concern is synthetic cannabis, starting at the beginning of 2012 in February 2012 and climbing through 2013. Current data suggest that calls to the Helpline peaked in June and July of 2013 before trending down toward the
end of that year. This is germane to the present report as that time corresponds with the introduction of the Psychoactive Substances Act in July 2013, and the resultant decrease both in outlets distributing synthetic cannabis products and in the actual range of available products themselves. The implications of these regulations and potential impact on the market and consumers are discussed in greater detail below. Graphically representing these data (Figure 1) more clearly illustrates the rise, peak and decline of calls to the Alcohol Drug Helpline through this period.

A comparison with calls received by the Alcohol Drug Helpline for other drugs further contextualises the call volumes noted here for synthetic cannabinoids. In Figure 2 (below) monthly call data to the Helpline comparing call volume as a percentage for synthetic cannabis, raw cannabis and alcohol, for the years 2012-2013, are depicted. Of interest is a possible interaction between cannabis and synthetic cannabis, which may relate to the seasonal availability of the former, thereby reinforcing the argument that the markets for these two products are closely linked. This issue will be taken up in the discussion. Incidentally the call volume for alcohol reflects a similar level to that identified by positive drug screening at the Auckland Community Helpline.

1.3.3.1 Reporting harms through existing surveillance

It is helpful to augment the quantitative Alcohol Drug data with more descriptive material gathered by individual Helpline counselors. Presented below in Table 2, these data were collected by Helpline staff to better characterise the callers’ experiences and to identify problem substances (Personal Communication with Carol Randal, Senior Counselor, Alcohol Drug Helpline, 12/2/14). Although not representing a systematic collection of data reported to the Helpline, Table 2’s
anecdotal information does provide a more detailed depiction of the nature of callers’ experiences. They are interesting for several reasons. Callers are not simply expressing concerns about their use, i.e. solely being worried about their habits. Rather, they are reporting a variety of, in some cases, severe symptoms and dangerous health conditions. Symptoms include agitation, paranoia, panic attacks, depression, anxiety, vomiting and tachycardia. More seriously, aggression, violence, seizures and suicidality also feature. Collectively many of these symptoms reflect consumers’ frequent use of synthetics and suggest dependence. The latter is underscored by the more serious symptoms commonly being associated with callers’ attempts to cease use altogether, and therefore are indicative of withdrawal, indicating physiological dependence. These withdrawals were reported to last from several days to a few weeks.\(^6\)

The anecdotal data are also interesting due to the inconsistency of their reporting. The second column in Table 2 records numbers of callers questioned per month, while the

<table>
<thead>
<tr>
<th>Date</th>
<th>Call #’s</th>
<th>%*</th>
<th>Sex</th>
<th>Age</th>
<th>Symptoms</th>
<th>Product</th>
<th>Negative Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar ‘13</td>
<td>32</td>
<td>30</td>
<td>M 26</td>
<td>17-40</td>
<td>Wdl, Ag, Vln, Para, Dep, Szur, Scd</td>
<td>K2, Anarchy Puff</td>
<td>Emp, $, Rel, Fam</td>
</tr>
<tr>
<td>April ‘13</td>
<td>25</td>
<td>23</td>
<td>M 18</td>
<td>15-40</td>
<td>Wdl, Ag, Anx, Tchy, Para, Pain</td>
<td>K2</td>
<td>Emp, $, Rel</td>
</tr>
<tr>
<td>May ‘13</td>
<td>27</td>
<td>23</td>
<td>M 18</td>
<td>20-40</td>
<td>Wdl, Ag, Agt, Anx, Pych, Para, Vom</td>
<td>K2</td>
<td>$, Fam, Rel</td>
</tr>
<tr>
<td>June ‘13</td>
<td>20</td>
<td>13</td>
<td>M 17</td>
<td>17-55</td>
<td>Wdl, Ag, Anx, Pych, Para, Vom, Dep, Szur, Scd, Pn</td>
<td>K2</td>
<td>$, Fam, Rel</td>
</tr>
<tr>
<td>July ‘13</td>
<td>13</td>
<td>9</td>
<td>M 9</td>
<td>15-60</td>
<td>Wdl, Pych, Dep, Szur, Pnc, Pn</td>
<td>K2</td>
<td>Rel</td>
</tr>
<tr>
<td>Aug ‘13</td>
<td>9</td>
<td>9</td>
<td>M 5</td>
<td>18-35</td>
<td>Wdl, Dep, Dpd, Szur, Pnc, Vom</td>
<td>SC</td>
<td>Rel, $</td>
</tr>
<tr>
<td>Sep ‘13</td>
<td>3</td>
<td>7</td>
<td>M 1</td>
<td>18-61</td>
<td>Wdl, Dep, Ag</td>
<td>SC</td>
<td>Rel, $</td>
</tr>
<tr>
<td>Dec ‘13</td>
<td>2</td>
<td>3</td>
<td>M 2</td>
<td>15, 26</td>
<td>Wdl, Szur</td>
<td>SC</td>
<td>General</td>
</tr>
<tr>
<td>Jan ‘14</td>
<td>14</td>
<td>?</td>
<td>M 10</td>
<td>13-23</td>
<td>Wdl, Dpd, Pych, Ag, Vom</td>
<td>Outbreak Anarchy White Rhino</td>
<td>$, Rel</td>
</tr>
<tr>
<td>Feb ‘14</td>
<td>17</td>
<td>?</td>
<td>M 13</td>
<td>19-56</td>
<td>Wdl, Ag, Anx, Dpd, Pych, Unc</td>
<td>SGT24 PB22 Karma Voodoo</td>
<td>$, Rel</td>
</tr>
</tbody>
</table>

* % of all calls for month (e.g. see Table 1 above) that data are based on

\(^6\) The issue of withdrawal from synthetic cannabinoid products is one some within the industry have been aware of for some time. Ironically a solution that had been discussed—the inclusion of an analogue of the anxiolytic cannabinoid cannabidiol (CBD) in synthetic products—was disqualified due to CBD being a constituent of Sativex®, a whole-cannabis extract medicine and controlled drug. See Appendix 3 for a discussion of this vis-à-vis withdrawals, by industry pharmacologist James Williamson.
third column depicts the previous column’s number as a percentage of all relevant calls logged for that month, as noted above in Table 1. Therefore percentages of anecdotal descriptions of all monthly relevant calls range from 30% in March 2013 to 3% in December 2013. No anecdotal data were reported for October and November, and numbers for total call data were unavailable for the first two months of 2014, at the time of writing. Helpline staff failed to specify exactly which synthetic cannabis products were being used by callers in August, September and December. These inconsistencies reflect the general state of synthetic cannabinoid data currently available in New Zealand, the collection and categorisation of which tend to be ad hoc. This problem was acknowledged by a Helpline supervisor, who noted she had had to push staff to record specifics from callers (Personal Communication with Carol Randal, Senior Counselor, Alcohol Drug Helpline, 13/2/14).

Nonetheless, the anecdotal data also show the impact of product changes in the market, some of which it might be assumed have resulted from the introduction of the Psychoactive Substances Act (2013) (hereafter PSA [2013]). Thus while the first half of Table 2 records the product ‘K2’ as being prominently associated with negative events reported by consumers, from July that product no longer features, except in historical utterances of callers. By the end of the data collection period other products, e.g. Voodoo, and quite specific substances, e.g. SGT24 and PB22, are reported. The latter likely also reflect the new legislation’s requirement for more accurate labeling on product packaging.

A final general point, concerning raw cannabis, needs to be made regarding anecdotal data from the Alcohol Drug Helpline. While Figure 2 above depicts a greater volume of calls identifying cannabis as the primary drug of concern, compared with synthetic cannabis products, the issues identified by users of raw cannabis appear to be less clinically serious than those identified by synthetic cannabinoid users as described in Table 2. Senior Counselor Carol Randal noted the following:

> Usually [cannabis] callers report disturbed sleep, feeling bad tempered, or grumpy, cravings, worry about friends still smoking near them. And many of our cannabis users are long-term users so have more than the physical stuff to deal with. None of the hideous stuff reported from SC. Of course SC isn’t cannabis at all as we know.

> Cannabis users report wanting to stop for various reasons – “over it”, “need to do something with my life”, legal reasons, drug test requirements, family pressure.

> — Personal Communication with Carol Randal, Senior Counselor, Alcohol Drug Helpline, 13/2/14

The above observation about cannabis’ lesser severity notwithstanding, it is also worth acknowledging earlier National Minimum Dataset (NMDS) information reviewed by the Ministry of Health, comparing hospital discharge data for raw cannabis and “synthetic cannabinoids” (Treasury, 2012). Contrasting with much of the information reviewed for the present report, data available for this earlier period (i.e. 2009-11), employed an encrypted form of the National Health Index (NHI) identifier, allowing the Ministry to link hospital discharge data with demographic information (age, gender, ethnicity, NZDep 2006 quintile), emergency department attendance data, along with information on secondary mental health and
addiction service use. The resultant linked dataset allows the Ministry to build a profile of drug harm risk, effectively using hospitalisation as a proxy for a certain level of severity.

In examining the NMDS data during 2009-11, the Treasury (2012:3) notes, “there were 37 people with hospital discharges involving legal highs, compared to 3161 for cannabis and 808 for stimulants. Compared to people with hospital discharges involving cannabis use, legal high users were younger (median age 23, compared to 30 for cannabis users), were less likely to be Māori (41% compared to 51% of cannabis users) and less likely to be living in an area of high deprivation (NZDep 2006 quintile 5) (27% compared to 40% for cannabis users).” While these data suggest there are some differences between consumers of synthetics and those of raw cannabis, they also imply that a considerably larger number of reported negative events were associated with the latter. However, this needs to be placed in context, with one means of doing so being to compare per capita consumption of each class of substance. Unfortunately as discussed below, this is problematic due again to limited sales volume data on synthetics.

Adding detail to this picture are data from two further drug harm surveillance organisations, the New Zealand Pharmacovigilance Centre (CARM) and the National Poisons Centre (NPC). In 2013 the Ministry of Health tasked the former with reporting on cases it had received, which described adverse reactions associated with synthetic cannabinoid use. As of July 27th 2013, CARM had been notified of six cases, with the first being received in April 2013 and the last by June 30th of that year. Table 3 shows the details of these cases. Of note is the rapid onset of symptoms following a single dose in four of the cases. In these four the patients exhibited symptoms (collapse; anxiety / tachycardia / depression; convulsions/acute renal failure; tremor / agitation / polydipsia [excessive thirst]) within 24 hours of a single dose. Three of the six also suffered renal necrosis or failure of kidneys, requiring a minimum of seven days hospitalization. Renal symptoms were associated with the use of Fu_Ked Up, K2 and Kronic. Overall, three of the cases had been notified to CARM by General Practitioners and three by hospital doctors.

Table 3: Six cases of synthetic cannabinoid harm reported to CARM, to June 2013

<table>
<thead>
<tr>
<th>Brand</th>
<th>No. of Cases</th>
<th>Hospitalised</th>
<th>Medically significant</th>
<th>Not yet recovered</th>
<th>Days of use</th>
<th>Gender* / Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>FU_KD UP</td>
<td>1</td>
<td>Yes</td>
<td>1</td>
<td>1</td>
<td>14</td>
<td>38</td>
</tr>
<tr>
<td>K2</td>
<td>3</td>
<td>Yes x 2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>13, 40, 16</td>
</tr>
<tr>
<td>Kronic</td>
<td>1</td>
<td>Yes</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>27</td>
</tr>
<tr>
<td>Unknown</td>
<td>1</td>
<td>No</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>38</td>
</tr>
</tbody>
</table>

* All cases were male

Regrettably for this data set cannabimimetics were NOT differentiated from non-cannabimimetics within the broader category of “legal highs”.

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7 Regrettably for this data set cannabimimetics were NOT differentiated from non-cannabimimetics within the broader category of “legal highs”.

The National Poisons Centre (NPC) provides a 24-hour/7-day toll free emergency phone service. It answers approximately 30,000 phone enquiries a year, with its principal role being to provide public and health care professional advice in acute poisoning situations. Along with CARM, the NPC was asked by the Ministry of Health in 2013 to provide data on enquiries relating to synthetic cannabis products. These data, in the form of monthly reports to the Ministry, provide the basis of the present discussion and are set out in Figures 3 and 4. The first of these (Figure 3) shows all calls to the NPC for the period January 2013 to January 2014. Of note is the peak in calls in August 2013, the month following introduction of the NPS legislation. With this new legislation it became mandatory for all products marketed as legal highs to have the NPC’s free phone number included on product packaging. The call volume to the centre is noticeably higher from July 2013.

As Figure 4 shows, however, the increased call volume prompted by the July legislation also altered callers’ reasons for contacting the NPC. Thus at the beginning of the period depicted, i.e. January and February 2013, all calls received by the centre were either by callers or their affiliates concerned that they had been poisoned. Subsequent to the July legislation this pattern was consistently altered, with approximately half of all callers only requesting information from the centre.

As is the case with the CARM data discussed previously, where callers contacted the NPC to register concern that they, or the person they were calling on behalf of, had been poisoned, symptoms frequently...
reported included nausea, vomiting, tachycardia, aggressive behaviour, sleeplessness and seizures. Moreover, severe symptoms including unconsciousness and kidney damage, were also described by people reporting both acute and chronic usage. Negative withdrawal symptoms were frequently noted by people attempting to cease use. Calls following the July legislation were less likely to mention the problematic brands K2 and Kronic than prior to July. Unfortunately, products were most commonly not specified by brand, with the generic ‘synthetic cannabinoids’ most frequently used to identify them. Finally, the majority of callers over the period surveyed were male, with monthly proportions ranging from 50% to 100% (average 72%).

Consistent with other New Zealand data, those from the NPC also suffer from inaccuracy and lack of detail. Aside from the limited details of product name brands (which may be due to callers themselves being confused over the product they are calling about), NPC data available for the present report included a number of duplicated call reports, calls which appeared to be hoax calls (some of which were noted as such), calls associated with accidental poisonings of animals and misidentified calls, i.e. calls noted as poisonings which on closer examination appeared to be solely requests for information. At least one call was listed as ‘poisoning/exposure’, where the caller noted an improvement in the behaviour of the person she was calling about, following their switch from cannabis to synthetics. Although these errors are few in number, due to the relatively small monthly call volumes (e.g. Figure 3), as a proportion they sometimes run at between 5-10% of monthly calls. This is significant as upon collation these uncorrected reports are forwarded to the Ministry of Health, who acknowledged they did not look specifically for incorrect data (Personal communication with Bruce Atmore, Principal Advisor, New Regulations Establishment Unit, 12 December 2013). Neither does the NPC appear to collect detailed data on the dosage associated with calls nor differentiate circumstances of use, with all calls described as ‘poisoning/exposure’ also denoted as ‘abuse’ in explanation of the reason for use. Once again this might, for some callers, be due to their inability to fully explain their situation. Nonetheless these are crucial data and the lack of their reporting is discussed subsequently.

Collectively the above data—MOH, Alcohol Drug Helpline, CARM and NPC—provide a broad brushstroke picture of harms through formal and informal medical and treatment surveillance, some of which lacks rigour. Even so these sources consistently suggest a variety of physical and psychological harms associated with the consumption of synthetic cannabinoid products in New Zealand. Examining the limited peer reviewed literature on harms extends their assessment into a finer grained analysis.

1.3.3.2 Published New Zealand studies discussing synthetic cannabinoids

Augmenting the formal and quasi-formal surveillance data discussed in the preceding section are a small number of published New Zealand commentaries and peer-reviewed articles of varying depth and quality. Amongst the former are three letters to the New Zealand Medical Journal reporting data from the NPC. The first of these (Schep, Slaughter, Temple, Nair et al., 2011) notes the rise of synthetic cannabinoid use in New Zealand over the preceding year, predicts health problems arising and
emphasises the need for regulations to limit harms. The authors suggest, however, that negative effects might be expected to be similar to those arising from the misuse of raw cannabis. The authors of a subsequent letter that same year (Schep, Slaughter & Temple, 2011) review twelve months of NPC calls concerning synthetic cannabinoids (n=72). They note a range of commonly reported symptoms, in rank order: tachycardia, vomiting, drowsiness, anxiety and agitation, tight chest, psychosis, hallucinations and chest pain, as well as less frequently reported unconsciousness and a single seizure. They observe that tachycardia was reported in excess of 50% of presenting patients. These latter authors (Schep, Slaughter & Temple, 2011) also observe that the increase in calls corresponded with a rise in media attention surrounding synthetic cannabinoid products and comment that one batch of a specific product had been contaminated with the benzodiazepine phenazepam. They conclude by noting “a dramatic fall in calls to the NPC” following the government’s prohibition of cannabimimetic analogues in August 2011.

Subsequently, in 2012 Schep and colleagues comment on a further rise of calls to the NPC, with reported symptoms acknowledged as differing from those associated with raw cannabis misuse and overdose, and varying slightly from the rankings reported in 2011, e.g. in this latter publication the rank order was: tachycardia, vomiting, agitation, drowsiness, psychosis, hallucinations, anxiety, headache, seizures and tremors. They note that increasingly Emergency Department staff are reporting aggressive patients and those presenting with symptoms of withdrawal. The product K2 was “overwhelmingly identified”, with the authors commenting that with its banning, along with related analogues, a decline in NPC calls should be anticipated (Schep et al., 2012).

During the period covered by Schep and colleagues’ letters, an article exploring the New Zealand experience with the synthetic cannabinoid JWH-018 and its associations with psychosis was published (Every-Palmer, 2011).9 The paper is interesting as it presents qualitative data from semi-structured interviews with 15 patients with serious mental illness in a New Zealand forensic and rehabilitative service. All 15 subjects were familiar with a locally available product, ‘Aroma’, containing JWH-018, with 86% reporting having used this. Patients commented on the product’s “potent psychoactivity, legality, ready availability and non-detection in drug testing as reasons for its popularity” (Every-Palmer, 2011). Most suggested it had replaced raw cannabis as their drug of choice and they had assumed the product was “natural” and “safe”. Anxiety and psychotic symptoms were commonly reported after use, with the author concluding that 69% of users exhibited symptoms consistent with psychotic relapse after smoking JWH-018. Despite commonly experienced negative psychological side effects, no subjects reported becoming physically unwell. The author observes, “[t]hree subjects described developing some tolerance to the product, but no one reported withdrawal symptoms” (Every-Palmer, 2011). The article concludes with the suggestion of the likelihood that JWH-018 might precipitate psychosis in vulnerable individuals and that “[p]eople with risk factors for psychosis

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9 Every-Palmer had published an earlier paper warning of the potential for synthetic cannabinoid products compromise the mental health of vulnerable populations. See Every-Palmer, S. (2010). Warning: Legal Synthetic Cannabinoid-Receptor Agonists Such as JWH-018 may precipitate psychosis in vulnerable individuals. Addiction, 105(10), 1859-1860.
should be counseled against using synthetic cannabinoids” *(ibid:152).*

Every-Palmer’s (2011) concerns regarding the association between the use of synthetic cannabinoid products and psychosis are supported by evidence from more recent research. In 2013 Glue and colleagues conducted a retrospective audit of admissions associated with use of the synthetic cannabinoid K2 (self-reported), to an acute psychiatric ward in Dunedin. In this study 17 patients collectively had 21 admissions between January and April 2013, representing 13% of the ward’s admissions over that period. For 4 of the patients the hospitalisation was their first, with 4 of the remaining 13 patients presenting with new symptoms and the remaining 9 having recurrences of pre-existing disorders. The authors describe symptoms as variable and including “psychotic (paranoia, thought disorder, disorganised behaviour), affective (anxious, depressed) disturbances, and/or intense suicidal thinking/behaviour. Mean duration of admission was 8.5 days, with significantly longer durations for those presenting with psychotic symptoms (13.1 vs 4.4 days)” *(Glue et al., 2013).* They concluded there was an association between K2 and “significant psychotoxicity”, indicating a “substantial risk associated with use of synthetic cannabinoids” *(ibid:2013).*

### 1.3.3.3 Summary of New Zealand literature regarding synthetic cannabinoid harms

Aside from limited articles examining non-clinical, i.e. more technical aspects of synthetic cannabinoids (e.g. see Ashton, 2012), the above cited publications comprise, to the present author’s knowledge, the only significant relevant peer reviewed material specifically reporting New Zealand data on synthetic cannabinoid harms. These and supporting international research were ably reviewed by the Ministry of Health (2013c), published online in October 2013.¹⁰ That document’s conclusions are entirely consistent with evidence informing in the present report and are therefore presented below verbatim:

The most important findings of this review are that:

- despite media reported high levels of use in some populations, there is a paucity of reports and research in the medical literature;
- most of the local and international published case reports are for psychoactive substances that are now prohibited from sale in New Zealand;
- there is a common set of adverse reactions reported across the range of psychoactive substances which may be attributable to all of the synthetic cannabinoids;
- symptoms including: tachycardia, agitation, vomiting, sweating, hypertension, fainting, hypotension, confusion, cramp, rhabdomyolysis, and breathlessness have been reported;

• while several of the adverse reactions reported for synthetic cannabinoids are similar to those reported for cannabis, the prevalence of some adverse events appear to be increased for synthetic products;

• some adverse events appear only to occur with the synthetics;

• the differences between synthetic cannabinoids and cannabis may be due to differences, or imbalances, in the effects of the constituents of each at tissue CB1 and CB2 receptors;

• several of the case reports for severe adverse reactions in the literature are in individuals who have substituted chronic synthetic cannabinoid use for moderate to heavy daily cannabis use to manage a legal risk or routine workplace testing;

• serious adverse events have been reported following acute exposure to synthetic cannabinoids;

• the underlying cause of the some of the severe adverse events of concern, specifically seizures and acute tubular necrosis, remain undetermined;

• due to the unregulated nature of the market, and in absence of quality testing systems, most published research has not been able to determine whether these adverse events are secondary to toxicity of the molecule, contamination of the active ingredient with other unidentified substances, or poor manufacturing methods leading to delivery of uncontrolled doses.

—Excerpted from The Safety Assessment of Psychoactive Products, Ministry of Health (2013c:2-3, emphasis supplied)

1.3.4 New Zealand legislation as a response to synthetic cannabinoid harms

Unlike the political reaction to BZP-harms, which saw that substance banned in 2008, legislative response to synthetic cannabinoids has instead taken the form of a set of regulations introduced through Parliament as the PSA (2013). This is consistent with the principle of Harm Minimisation, which provides the philosophical compass for New Zealand’s National Drug Policy (NDP).11 At the time of writing this response to NPS, i.e. regulation rather than prohibition, is globally unique to New Zealand.

In part this may reflect legislators’ awareness that manufacturers of these synthetic substances are able to rapidly create and circulate new products, which circumvent the piecemeal bans implemented in other jurisdictions (see Bright et al., 2013). However, the advent of New Zealand NPS legislation also suggests that policy makers have sought to avoid repeating historic mistakes of prohibition—most recently in relation

11 The NDP is currently under review and while Harm Minimisation apparently remains its ‘founding principle’, the authors of the recently disseminated discussion document for the review—A New National Drug Policy For New Zealand: Discussion Document—appear confused about the core tenets of harm minimisation, i.e. that some people will continue to use drugs and therefore the strategy is to reduce drug harm while accepting use and not requiring a reduction in use per se. The issues paper (Ministry of Health, 2013a) may be downloaded at: http://www.health.govt.nz/publication/new-national-drug-policy-new-zealand-discussion-document. For a discussion on the definitional problems of harm minimisation (more widely referred to as ‘harm reduction’) see Wodak, A., & Saunders, B. (1995). Harm reduction means what I choose it to mean. Drug and Alcohol Review, 14, 269-271.
to BZP—whereby banned products immediately reappear on the black market, even less controlled and subject to greater misuse. In the latter case, for example, despite being prohibited in 2008 BZP remains available illegally in New Zealand. In fact since banning, according to the IDMS annual survey of frequent drug users, ease of availability actually increased after a dip following the initial ban and is now relatively stable (Wilkins et al., 2013).

In contrast to the approach adopted regarding BZP, it is clearly the incumbent Government’s view that the simple prohibition of synthetic cannabinoids would potentially create further harm and therefore that regulation is a more appropriate response to negative consequences of availability. This is explicit in the actions of the Ministry of Health, which has worked assiduously on implementing the new regulations and in close consultation with at least some sectors of the Industry (Treasury, 2012:11 et passim).

1.3.4.1 Background to the new regulatory regime for NPS

Leaving aside the historical issues noted above, the contemporary origins of the PSA (2013) and related regulatory regime derive from the Law Commission’s 2011 review of the MoDA (1975). As the Ministry notes in its subsequent Regulatory Impact Statement (Ministry of Health, 2012:1), the Law Commission identified two interrelated problems with the then status quo regarding NPS: that these were available with effectively no control over ingredients, dose, place of sale and purchase age; and, that the onus to identify such substances and subsequently determine their harmfulness before restricting them is clearly on the Government. In its response to the Law Commission’s (2011) review,

[T]he Government agreed to consider the development of legislation for psychoactive substances posing a low risk of harm, which may require the supplier or manufacturer to apply to a regulator for approval or otherwise demonstrate that it meets required standards before substances can be manufactured, imported or distributed, subject to regulatory impact analysis (Ministry of Health, 2012:ibid).

In the view of the present author this strategy, codified with the subsequently passed PSA (2013), represents a fundamental shift in how New Zealand legislation engages with novel psychoactive products and by extension the psychoactive experience itself. It should be noted, however, that the seed of this recent legislation may be found in the Misuse of Drugs Amendment Act 2005 (MODAA 2005), which makes provision for the regulated sale of psychoactive substances but which, up to and including the present time, does not list any.\(^\text{12}\) Nonetheless, it now appears that a legislative space has been created for recreational psychoactive substances other than those

\(^{12}\) The notion of legislative ‘space’ to meet a legitimate need for alternative psychoactives was originally mooted in New Zealand in 1970 via a Board of Health Committee enquiry into recreational drug use, set up to inform the subsequently enacted MoDA (1975). That committee noted, “[T]hat some people who do meet the canons of reasonable mental health might decide that it is quite proper to use drugs for pleasure in private, and that, as a result, the number of people using psychoactive drugs for this purpose could rise to a level at which it would challenge the accepted social code” (Board of Health Committee, 1970:83). For a detailed analysis of the impact of the Committee’s two reports on New Zealand drug policy, with reference to cannabis, see Noller (2008:67-98).
traditionally available, i.e. alcohol, tobacco and caffeinated beverages, with the proviso that consumers are subjected to at most a low risk or low level of harm.

Interestingly, the threshold of ‘low risk’ set by the Ministry’s adaptation of the Freiburg framework (see Appendix 1 and section 1.3.4.2) recognises that the harms associated with alcohol would disqualify New Zealand’s most popular psychoactive drug from approval. In other words currently available data suggest it would exceed a ‘2’ rating under the safety assessment rating system (Ministry of Health, 2013c:6). The harms of alcohol are discussed in more detail in Part 2 of this report.

Thus, in summarising the aims of the (at that time proposed) PSA (2013) the Ministry’s Regulatory Impact Statement (2012:7) notes that the primary objective should be to develop a regime able to deal with the ‘rapidly evolving market in psychoactive substances, balancing the risk of harm to individuals and society with the demand for access to such substances”. Further, that the regime should:

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

(\textit{op. cit.} my emphasis)

Therefore, while obligations are placed on the psychoactive industry to ensure the production, marketing and sale of low risk products only, the regulation and oversight of this regime lies squarely with the Government. Moreover, the commitment of both parties to cooperate in developing and implementing such a regime is explicit in the Ministry’s Regulatory Impact Statement, with frequent references to both consultation with industry representatives and reference not only to the latter’s obligations, but also to its needs (\textit{ibid:} 11 \textit{et passim}). This process extends to all areas of the proposed regime, from product testing and manufacturing to marketing. Industry engagement with proposed processes appears to have been generally supportive, even to the extent that some within the industry argued for a more restrictive retail distribution model “that would allow them additional controls over who may access their products” (\textit{ibid:} 25).
1.3.4.2 Implementing the new regulatory regime: A practical application of harm minimisation

Immediately subsequent to, and following the enactment of the PSA (2013) and the establishment of the Psychoactive Substances Regulatory Authority (the Authority) within the Ministry of Health, a set of proceedings were implemented consistent with the core objective of minimising harms associated with the consumption of synthetic cannabinoid products. These include but are not limited to:

- developing a metric of harm (Freiburg scoring framework, [Hermanns-Clausen et al., 2013]) by which all extant products could be assessed, using a strategy applied to the regulation of medicines and chemicals, e.g. $Risk = effect \times exposure$ (excerpted in Appendix 1 of the Ministry’s (2013c) discussion of scoring);

- applying the above to immediately permanently remove products from the market that exceeded the specified threshold of the adapted scoring framework (i.e. all products scoring more than 2 on the framework);
  - this resulted in the reduction of an estimated 200 available products to approximately 50;

- giving interim approval until regulations passed (passing of the PSA [2013]) for remaining products, with on-going assessment of harm based on data received from the NPC and CARM, the latter resulting in:
  - revoking of interim approval for a further 6 products September 26 2013;
  - revoking of interim approval for a further 5 products January 2014;

- sale of psychoactive products prohibited from dairies, convenience and grocery stores, supermarkets, service stations and liquor outlets, as at July 18th 2013;
  - resulting in reduction of retail outlets from an estimated 4000 to 153 at the time of writing;

- sales and possession limited to 18+ years;

- strict advertising controls and product labelling:
  - advertising only permitted at point of sale;
  - no labelling or advertising allowed to appeal to minors;
  - products must be labelled with health warnings, a list of the active ingredients, contact details for the manufacturer or distributor, and the telephone number of the National Poisons Centre;
  - provision of a toll-free help and information phone line dedicated to synthetic cannabinoids (post The Act, 2013);
  - no internet sales of unapproved / non-interim approved products;

The *Manufacturing Code of Practice* requires manufacturers to demonstrate their ability to produce psychoactive substances and products that:

- are manufactured in Good Manufacturing Practice (GMP) licensed facilities;
- are manufactured to defined quality standards;
- use ingredients that comply with internationally established standards;
- comply with a set of specifications agreed by the Authority as part of the product approval (ibid:1).

Applicants will be required to submit any products for a full licence under the code and in compliance with all stipulations of The Act. The *Manufacturing Code of Practice* requires a staged implementation schedule, an overview of which is set out in *Figure 5*, with a typical final deadline for implementation across various components being April 22\textsuperscript{nd} 2015.\textsuperscript{13} The *Code of Practice’s Appendix 1* (Ministry of Health, 2014:6-13) specifies the details of compliance for those participating in the NPS industry in New Zealand, across the timeline described below in *Figure 5*. The regulatory requirements are strict, numerous and voluminous and will likely eliminate all but the most determined industry players from the marketplace. Thus, while the Ministry is unable to predict with any certainty how many products might be submitted for approval it nonetheless suggests that this could be as many as 10 over the first two years, though perhaps only “one or two” at the end of the first year (Ministry of Health, 2012:18).

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\textbf{Figure 5: Overview of Code of Manufacturing Practice Implementation*}

*Source: Ministry of Health (2014:2)*

\textbf{1.3.4.3 Other vectors for harm: Internet sales, LAPPs and minimum pricing}

Some potential vectors for harm remain to be accounted for by the broad array of legislation and regulations described above. The three discussed here are unlikely to be the only outstanding areas of concern. However, they suggest themselves for the

\textsuperscript{13} Full details of the *Manufacturing Code of Practice* (Ministry of Health, 2014) may be accessed online. The reader is directed to the *Code’s Appendix 1*, which summarises all requirements. See [http://www.health.govt.nz/publication/psychoactive-substances-code-manufacturing-practice](http://www.health.govt.nz/publication/psychoactive-substances-code-manufacturing-practice)
present report due to their profile in current media discourse and as a result of the author’s investigations.

The PSA (2013), for example Section 53 generally, requires certain compliances regarding internet sales. Other sections relevant to the internet include:

- limiting sale from websites designed solely for that purpose, by licensed retailers (Section 56c);
- those aged 18 years and older (Part 3, Section 48);
- restricting websites or product advertising such that minors do not view or access it, and requiring that appropriate health warnings are visible (Section 101c i-iii).

The latter two points are of particular significance with evidence accruing that the monitoring of internet sales and access to these by minors is proving problematic. Anecdotal reports from Dunedin suggest people as young as 15 years have been accessing synthetic cannabis produces from online sites (personal communication between the author and Dunedin Needle Exchange staff, 27 March 2014). Similar reports have appeared in the media (Smallman & Leaman, 2014), with the suggestion that social media sites are being used as points of contact between retailers and teenage customers. In the latter example it is claimed that internet access to ‘legal highs’ has resulted from the Hamilton City Council’s banning of their sale within the city via its Local Approved Products Policy (LAPP).

The situation with LAPPs is a complex one, with there seeming to be a legal ‘disconnect’ between potential community and council preferences on the one hand, where these are hostile to the establishment of a local NPS market, and binding central government legislation on the other. Thus Section 68a-c of The Act allows for councils to specify the location of NPS premises with reference to other premises and to specific ‘sensitive’ premises or sites, e.g. schools, kindergartens and places of worship. However, in a submission to all New Zealand councils regarding LAPPs (Appendix 4), industry organisation The STAR Trust notes that local authorities may not create other forms of retail regulations, prohibit the retail of approved products within their districts or regulate internet sales within a district (see submission Section 13a-c; The STAR Trust, 2014).

At the time of writing (early April 2014) this issue is currently before the Courts in relation to the Hamilton City Council’s banning of NPS sales within the city. Moreover, the scenario described above regarding a shift from point of sale purchase at, i.e. from a physical address, to potentially less controlled internet sales, is precisely the situation The Act was designed to avoid. The negative consequences of moving beyond the spirit of The Act—to avoid prohibition—is evident from the article above (Smallman & Leaman, 2014), which also describes how clients no longer able to access NPS within Hamilton travel to nearby settlements—in this case Te Awamutu—to make purchases.

Interestingly, in a conversation with a Dunedin retailer, it was suggested to the author that more positive outcomes for consumers are likely if retail outlets are in well
patronised shopping precincts, where greater expectations are placed on a good quality of service by staff and appropriate comportment of customers. By pushing outlets to the fringes of retail zones, it was argued that it is more likely that poor retail practices would prevail (personal communication between the author and staff at Cosmic Corner, Dunedin, 29 March 2014). Nonetheless the issue of LAPPs remains a vexed one with, for example, South Island local authorities struggling with the new legislation. Thus Radio New Zealand recently reported Dunedin mayor Dave Cull as suggesting the NPS legislation is “a copout and now it's clear it is a mess, because councils have to define areas of sale but the Ministry of Health grants product licences separately” (Radio New Zealand, 2 April 2014).

The third vector of harm is somewhat simpler than the issue with LAPPs, though it also has implications for underage access to NPS. This concerns the issue of price, specifically the consequences of NPS being available at a low cost. Again, while The Act prohibits the gifting of NPS products or their inclusion in other special offers to purchasers (Section 54(1) a-c), it does not specify any minimum prices. This is potentially significant if one accepts the argument that the NPS market—and especially the synthetic cannabinoid market—owes much of its popularity to the already large domestic raw cannabis market. With the price of raw cannabis stable at approximately $350 per ounce, i.e. $12.50 / gram (Wilkins et al., 2013:168), the availability of a legal, potent, low cost alternative becomes very attractive.

This situation is seen with anecdotal reports suggesting that synthetic cannabinoid products are being sold at discounted rates for, e.g. $10 / 2.5 grams. To substantiate these claims the present author visited several Dunedin shops and noted products available at comparable prices to the above, e.g. one premise was selling 7 grams of a product containing PB-22 for $30, i.e. $4.30 / gram. In a market where the alternative product (raw cannabis) costs almost three times as much and is illegal (e.g. potentially difficult and / or dangerous to access, of unknown quality and, if consumed, and will place the user outside the law and possibly cause them to fail a workplace drug test), the option of a legal much cheaper alternative is generally more than attractive, as noted above, but particularly so for young people likely to have less disposable cash. This dynamic suggests, therefore, that some kind of mandatory minimum pricing regime for NPS would be appropriate (e.g. some outlets impose their own minimum prices) if the intent of The Act is to maintain a harm reduction focus, one component of which would be to limit uptake of any psychotropic, be it legal or illegal.

1.4 Discussion

A useful starting point for the present discussion is to acknowledge the currently recognised harms experienced by consumers of synthetic cannabinoid products, as well as medical, psychiatric and drug treatment services in New Zealand.

Having briefly reviewed the relevant international literature and in greater detail, the New Zealand literature and supporting data, types of domestic harms generally appear to be consistent those experienced overseas. In agreement with the Ministry of Health’s (2013c:2-3) Safety Assessment of Psychoactive Products (Section 1.3.3.3) we noted a common set of adverse reactions across a range of synthetic cannabinoid products. Symptoms included: tachycardia, agitation, vomiting, sweating,
hypertension, fainting, hypotension, confusion, cramp, rhabdomyolysis, and breathlessness. Although several of these were similar to symptoms reported for raw cannabis, some were more frequently reported for synthetics, e.g. tachycardia was reported in over 50% of presenting patients (see Schep, Slaughter & Temple, 2011), while others appeared to only occur with the synthetics. Severe symptoms were reported by chronic users of raw cannabis who had substituted synthetics to moderate cannabis use or to manage risk exposure to drug testing. Other reports noted severe symptoms for acute use and single exposure. Finally, and perhaps this is a lack in the Ministry’s (2013c) otherwise thorough report, it seems likely that some populations, e.g. mental health clients and under 18’s, might be particularly at risk.

It must be recognised, however, that the preceding paragraph presents an accretion of harms, in other words a compilation of reported harms over time. Similarly the present document has described cumulative reported harms over an approximately two-year period (i.e. 2011-13). How these harms translate into an actual magnitude of risk for the domestic landscape is difficult to calculate. Therefore it may be misleading to suggest that New Zealand consumers are currently exposed to all of the harms described above, at least in terms of likelihood. For example, as the Ministry commented in its assessment of harms (2013c), a number of negative events have been linked to products subsequently banned in New Zealand. Alternatively, even if exposure to all of the reported harms is currently a risk for consumers, the prevalence of these or frequency of exposure may have changed over time. There are a number of reasons for this, some of which are noted in official documents such as the Ministry’s (2013c) Safety Assessment, while others are implicit in legislative actions subsequent to that document (for example), as well as in on-going data collection and reporting.

A central strand in the global narrative of synthetic cannabinoid harms is the market’s dynamism. Therefore, while products identified as harmful historically have been removed through ad hoc legislation, new products rapidly take their place, with no guarantee of any greater safety. In New Zealand’s case legislators recognised the inefficacy of such piecemeal regulation and reacted with a stepped up response culminating in the PSA (2013). Hence rather than a reactive approach, with authorities denying the legitimacy of the phenomenon and thereby awaiting the appearance of the next suite of products to evaluate and potentially ban, the dynamism of the NPS market has been countered in New Zealand by accepting the possibility of these products, but only on increasingly stipulated terms.

This new strategy has had the effect of reducing the exposure to harms per se, e.g. through reducing retail outlets and product numbers, and also of reducing the possibility of future harms, e.g. through requiring a strict manufacturers’ code of practice. Moreover, the integrity of this process has been established via significant consultation with the industry, or at least those sectors within it willing to engage. This appears to have resulted in the growing collective ownership by Government and industry, entailing both opportunity and obligation, of a new market for novel psychoactives presenting at most a low level of harm.

As Figure 6 (below) shows, the evolution of the changing profile of synthetic cannabinoid harms in New Zealand can therefore be followed through legislative developments, public health surveillance, and consumer and industry responses to these. Understanding this process and the mechanisms it contains as emergent, is
essential to discussing the implications of synthetic cannabinoid harms in the New Zealand environment beyond the short term. Hence it is useful at this point to briefly reiterate the rise of synthetic cannabinoid products as a new phenomenon in the recreational drug market and concomitant issues including harms.

Prior to the PSA (2013), and quite possibly on the backs of the earlier BZP and long-established New Zealand raw cannabis markets, synthetic cannabinoid products rapidly gained ground as a type of non-traditional psychotropic (i.e. not alcohol, caffeinated beverages or tobacco). These products had been available from at least 2009. However, during the period 2010-2012, there appears to have been a burgeoning interest in them, with increasing reports of problematic use. Evidence of this rapid growth and associated problems comes from public health surveillance including the IDMS, NZ-ADUM, the Alcohol Drug Helpline and the NPC, with the two former of these reporting zero to significant frequency and prevalence of use between the years 2010-2011 (Wilkins et al., 2012). The data in section 1.3.3 have described this in detail.

At this early stage there was limited knowledge about the substances and their likely effects. For example, writing in 2011 NPC staff suggested that negative effects might be expected to be similar to those associated with the misuse of raw cannabis (Schep, Slaughter, Temple, Nair et al., 2011). In their subsequent review of the NPC’s data for 2011 (72 calls over 12 months), Schep, Slaughter & Temple (2011) drew attention to a high level of negative events, the contamination of one batch of product with a benzodiazepine and the dramatic drop off in calls following the banning of cannabimimetic analogues in 2011. While calls again climbed and actually peaked in July / August 2013, Dr Schep (NPC) comments in subsequent monthly reports to the Ministry that a downward trend of calls and reported negative incidents is occurring. Schep and colleagues (2011) also commented that the NPC’s increase in calls corresponded with media attention to the issue, a phenomenon subsequently reported in Australia (Bright and et al., 2013).

Figure 6: Synthetic cannabinoid harm reduction through legislation, surveillance and industry compliance

<table>
<thead>
<tr>
<th>Timeline</th>
<th>Legislation</th>
<th>Information / Data</th>
<th>Actions</th>
<th>Outcomes (Available products)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011-13</td>
<td>• Devel PSA Bill</td>
<td>Literature, consultation</td>
<td>Temp Class Drug Notices</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>• PSA (2013)</td>
<td>-ve event surveillance</td>
<td>Reduce retail &amp; products</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>• est Reg Authority</td>
<td>NPC, CARM, other</td>
<td>Interim licenses</td>
<td></td>
</tr>
</tbody>
</table>

| 2014     | • Adapt risk assessment | NPC, CARM, other | 6 licenses revoked Sept ‘13 | 42   |
|          | • (Freiburg framework) | Industry sales stats | 5 licenses revoked Jan ‘14 |      |
|          | • Manufacture Code of Practice | Producers apply | Part compliance Jan ‘14 |      |

| 2015     | • Psychoactive Substances EAC | Full compliance April ’15 | 2-10  |
|          | • Regulatory Authority | Retailers assessed Aug ’16 |      |
We have also noted how the inefficacy of a piecemeal legislative response appears to have been recognised by Government. Over the period 2011-2013 authorities responded to the Law Commission’s (2011) review of the Misuse of Drugs Act (1975) by heeding its suggestion that ad hoc legislation would not restrict such a dynamic market and that Government nonetheless had an obligation to appropriately implement some form of control. This led directly to the assembling of a more formalised, targeted surveillance strategy, the development of a risk assessment tool (an adaptation of the Freiburg framework) and, with the passing of the PSA (July 18\textsuperscript{th} 2013), an immediate reduction in retail outlets (from 4,000 to approximately 170) and individual product numbers (from approximately 200 to 43). The initial reduction was subsequently added to by the permanent revoking of a further 11 product licenses in September 2013 and January 2014. As Figure 6 indicates, by August 2014 it is likely there will be very few legally available synthetic cannabinoid products, with a predicted maximum of 10 by 2016 (Ministry of Health, 2012).

Two caveats do exist, however, regarding calculating the magnitude of harms, both per product and across the whole synthetics market. These relate to the calculation of harms, based on the Freiburg framework, i.e. $\text{Risk} = \text{effect} \times \text{exposure}$. As noted in Appendix 1, the calculation of exposure is achieved by using product sales data as a proxy, in combination with reported negative events. In the case of sales data, the Ministry suggests that this has the weakness of overestimating the numbers of people using a given product (Ministry of Health 2013c:5), i.e. their calculation may be less sensitive to harms per product than appears. This is because, for example, a smaller number of individuals might be consuming a large dose or more frequently than anticipated.

The above situation is compounded by the nature of sales reporting to the Ministry, an admittedly difficult process due to commercial sensitivity of the data. Thus during the preparation of this report, an Official Information Act (OIA) request to the Ministry resulted in the provision of documentation noting the figure of 2.7 million ‘units’ being claimed as distributed to retailers during 2013. These units, however, are actually packs of product, with the median weight being 2.5 grams for the 52 interim approved synthetic cannabinoid products listed on the Ministry’s website.\footnote{A crude descriptive analysis of product pack weights was undertaken, with the average being 3.7 grams. However, there were several outliers (e.g. weights ranged from 1.3-28 grams; SD 4.1). Hence the median weight, 2.5 grams, was preferred. The list of products is available at: \url{http://www.health.govt.nz/our-work/regulation-health-and-disability-system/psychoactive-substances/interim-product-approvals}}

Further complicating matters is that the contents of these ‘units’ represent multiple acts of consumption, i.e. each pack, depending on its contents’ strength, will provide the consumer with a certain number of ‘hits’. Very speculatively—and based on consultation with industry scientists, retailers and customers—the number of ‘hits’ per 2.5 gm pack might range between 15-25. One then needs to consider what the ‘effective dose’ is per product, i.e. that dose producing a noticeable or preferable effect. With alcohol, for example, this is proposed to be three standard drinks for a 70-kilogramme adult or approximately 33 grams of pure alcohol (Gable, 2006). With synthetic cannabinoids being more concentrated than alcohol it might be that two or even one ‘hit’ represents the effective dose. Thus in alcohol terms, a recorded ‘unit’ of a synthetic cannabinoid product might represent a large bottle of beer, a bottle of

\[14\]
wine or a bottle of spirits, thereby significantly complicating any analysis of harms relying on reported sales volumes.

This issue contributes significant weakness to the present analysis. Moreover, while attempts were made to contact leading individual companies to access such data (Appendix 2), only one company (Stargate International) provided information.\(^\text{15}\) Given the lack of response that partial data set has not been included in this report.

The second issue involves reported negative events, with the Ministry generally relying on data from the NPC and CARM. In their safety assessment discussion document they note:

> The lack of accurate data on adverse effects occurring in the community, as opposed to reported to the agencies such as the NPC, is a second recognised weakness in the risk framework. Research has demonstrated that calls to national poisons and pharmacovigilance centres are a subset of all events and effects occurring. These data significantly underestimate the actual rate of adverse events occurring in a community.
> —Ministry of Health, 2013c:5

This again underscores the embryonic nature of current NPS harm surveillance and assessment, and stands in stark contrast to more developed systems and data streams, e.g. those tracking alcohol harms. As noted previously and as discussed in greater detail in the Alcohol section below, current data on alcohol would, if assessed within the adapted Freiburg framework, disqualify it from the market.

While limited synthetics-related data (harms and sales) are acknowledged by the Authority as a weakness in its safety assessment process, it comments that the data it does make use of are the best available and that having an awareness of the surveillance system’s faults allow it to make provisions for these inaccuracies. It notes also that reporting rates per product may be subject to stimulus from media and other interest in products (Ministry of Health, 2013c:5). As discussed above this has previously been noted in New Zealand (e.g. Schep, Slaughter & Temple, 2011) and Australia (e.g. Bright \textit{et al.}, 2013).

Notwithstanding the previous observation, as an addendum to the data already provided, some recent anecdotal information tends to substantiate the view that at least the prevalence of negative events is reducing. Writing in the \textit{New Zealand Medical Journal} in December 2013, Evan Mason (Clinical Lecturer, Department of Psychological Medicine, Otago University), reports a seeming reduction in synthetic cannabinoid presentations and the emergency psychiatric ward Glue and colleagues (2013) earlier reported from. Mason notes “from early April to the end of October, 79 out of 1702 attendances” involved synthetic cannabinoids. He noted 56/856 from April to June (6.5%) and 23/846 from July to September (2.7%). This reduction from before to after the legislation reinforces its impact and a decline at least for this site, of admissions for acute problems. We have also previously noted Dr Leo Schep’s comments in monthly reports to the Ministry, that NPC call data indicate a downward trend in poisoning incidents.

\(^{15}\) Other companies contacted were Enjoi Products, Lightyears Ahead, NZ Nutritionals and Tai High.
The legislative impact on retail outlet and product numbers, as a proxy for reduced harm exposure, has also been acknowledged in areas where concern over availability of synthetic cannabinoid products had been expressed historically. Thus the Oamaru Herald reports comments from Waitaki MP Jacqui Dean regarding the positive consequences of reducing availability of products and access to a dedicated free call Hotline (Oamaru Mail, November 4, 2013). Having noted this, during preparation of this report the Oamaru Police were contacted regarding their view of the impact of synthetics following the legislative changes in July 2013. They claimed no obvious change in the negative consequences of synthetic cannabinoid products, specifically mentioning that these seemed to be strongly associated with the theft of vehicles and aggressive interactions with offenders, when confronted (Personal communication between the author and Senior Sergeant Jason McCoy, 14 March 2014).

Other anecdotal reports similarly concern environments where there have apparently been changes in reported non-medical negative events associated with synthetic cannabinoids. For instance, it has been reported by Police in more than one location that it might actually be preferable to have an NPS outlet in that area as potential consumers instead source products elsewhere, where there is less control over quality and content, and possibly greater risk to the purchaser, i.e. the recognised harms attendant to the illegal drug market.

The implications for harm, where uneven access occurs despite a legally regulated market, were further explored anecdotally with regard to internet sales, LAPPs and minimum pricing. Media reports and personal communication between the author and harm reduction organisations suggested that where point of sale access is limited (e.g. through customers’ age or proscriptive LAPP implementation), consumers seek access elsewhere. If purchasing online, underage consumers might avoid detection due to poorly developed monitoring and the use of social media to circumvent controls. In this regard, following consultation with STAR Trust Director, Grant Hall, the present author visited a Dunedin retailer recognised for its high quality practices around appropriate identification of clients. Although comprising only a small percentage of all sales, this retailer required all customers purchasing from its internet site to provide photo ID indicating date of birth, e.g. drivers licences and passports. Clients could hold IDs next to their faces, photograph themselves and email the result to the retailer. Similarly strict criteria prevailed at the retail outlet’s actual premise, along with notices declining access to parents accompanied by children.

This retailer was also adamant that the licensee should always have a significant role in the business, i.e. they should be on-site a majority of the time. This would then necessitate their commitment to the appropriate control of their business. They suggested that many local businesses did not follow this approach, with the potential result that if poor compliance occurred, a less significant employee might be fined but the business itself would not be at risk from loss of licence.

Inappropriate access and increased consumption appear to be exacerbated by low pricing of some products at some outlets. Thus in Dunedin the author corroborated reports of products being sold for approximately $4.50 / gram by visiting local shops. Low prices were by no means universal, however, with other outlets imposing voluntary minimum pricing equating to about $11 / gram, approximately the price for which raw cannabis can be purchased on the illegal market. In the context of The Act
and in the knowledge that in excess of 95% of synthetic cannabinoid consumers are likely to have previously consumed raw cannabis, it seems prudent that until synthetic products can clearly be shown to be less harmful than raw cannabis, the price of synthetics should not be lower than for raw cannabis.

The above comments notwithstanding, however, other retailers suggested prices lower than those for raw cannabis might be desirable. For instance the retailer noted above regarding internet sales and IDs, suggested that pricing synthetic cannabinoid products lower than raw cannabis had been promoted by local Police. The latter apparently felt this would push gangs away from retailing cannabis and thereby undercut their financial operations. The particular retailer in question claimed that this was happening locally and noted also the advantages of avoiding interaction with criminal gangs. Several customers at this outlet were questioned regarding access to legal synthetics versus illegal cannabis, will all agreeing they preferred legal access for reduced risk and quality of product. The Police have not been approached for confirmation.

Finally, while strategies to reduce harm have clearly been driven by Government, it is evident that they have benefitted from significant consultation with the NPS industry (e.g. Ministry of Health, 2012). Some of these have proven unproductive, for example the idea that including the cannabinoid CBD in products might ameliorate negative effects including psychosis and anxiety. This was discovered to not be an option due to CBD being a controlled drug as a consequence of its inclusion in medicinal cannabis product Sativex® (see supra note 6 and Appendix 3).

This issue of the tension between legislation / regulations and the industry, characterised by one commentator as ‘unintended consequences of the legislation, received significant comment from industry personnel interviewed during the preparation of this report. In part concerns related to the piecemeal implementation of legislation prior to The Act, whereby the banning of products resulted in new products with potentially worse negative effects taking their place. One commentator also claimed various government agencies had different attitudes to the industry. They noted a more sanguine approach by the Ministry of Health, who seemed committed to a regulatory approach due to the failure of earlier attempts to shut down the emerging market. In contrast they described an almost haphazard approach by NZ Customs, suggesting that at one point a Customs focus on white powder over a period of months meant that stocks of a product with a lesser harm profile were held up while a potentially less safe oil-based product was allowed to be imported. Several examples of this were provided by one industry individual, who commented that “we weren’t given the opportunity to use our best and safest compounds” before the NPS Bill (2013) was enacted. They observed also that while industry surveillance of market responses to their products indicated that other extant but unlicenced products would further reduce problems, the ‘inflexible’ structure of present legislation meant that these potentially safer products were locked out of the market.

The problems noted above were also signaled by consumers, some of whom contacted manufacturers regarding specific products that had been removed from the market. In one case several amputees individually contacted a particular manufacturer following the banning of a product that they claimed had proven extremely efficacious for neuropathic pain, i.e. more so than prescribed pharmaceuticals and raw cannabis.
These individuals even asked if some private arrangement could be made, when told that the product had been permanently removed.

Finally for the industry, there was concern reported about regulation where it focused on removing products rather than compounds from the market. One person interviewed noted that a specific product had been removed from the market but that in their view, one of the compounds within that product was of particular concern, possibly in the context of chronic use. They claimed that they had expressed their concerns to the Ministry but felt these had not been listened to.

In general, it appears that a range of stakeholders, e.g. communities, local authorities, consumers, retailers and industry, consider that they have less than satisfactory engagement with the Regulatory Authority than they would prefer. However, it does need to be stated for some of those groups, that there seems to be a resistance to engage with the spirit of The Act and what its authors intended, i.e. a public health response incorporating harm minimisation rather than simple prohibition. Collectively this may signal a lack of education about the intent of The Act and accompanying regulations, something commented upon by retailers in particular.

At a more macro level, however, some within the industry appear also to have engaged independently with the anticipated obligations implied by the PSA (2013). For example, on its Internet homepage industry representative group The STAR Trust invites retailers and manufacturers to join an entity called the Psychoactive Industry Training Association (PITA). Membership requires compliance with the PSA (2013) and agreement to a code of conduct, which includes a protocols compliance audit for retailers. The STAR Trust’s site is encouraging when compared with some liquor industry equivalents. However, the site falls short when compared to others, some of which offer links to applications that allow visitors to assess how safe their alcohol consumption is, e.g. DB Breweries’ Our Responsibility page links to the cheers.org.nz site.

While The STAR Trust’s site may currently appear underwhelming in terms of acknowledging NPS and, specifically, synthetic cannabinoid harms, it should be recognised that both the NPS industry and related compliance regulations are extremely recent. By comparison New Zealand’s first commercial brewery opened in Russell (then named Kororareka) in 1835. Nonetheless, given the increasingly detailed body of knowledge about synthetic cannabinoid harms, the growing public health surveillance system feeding into this and the groundswell of negative public opinion about synthetics, it seems reasonable that The STAR Trust, at the very least, develops an online help and support package for customers of its member organisations. This could readily be incorporated into PITA’s membership requirements, particularly at the retail end of the chain. Ideally any affiliated business or company would provide online access to the same suite of information and support, with linkages to independent resources, including local services for businesses in any given area. Through PITA, The STAR Trust could extend its consumer support by offering formal training in relevant skills for frontline staff of retail outlets. Areas to focus on might include but not be limited to:

16 http://www.thestartrust.org/pita
18 See http://en.wikipedia.org/wiki/Beer_in_New_Zealand#History
• record keeping concerning customers making multiple daily visits;
• developing skills to identify intoxicated customers and those with potential problems;
• staff de-escalation training for difficult interactions with customers;
• provision of literature and other resources relevant to substance use problems;
• developing a knowledge of local services and identifying sympathetic contacts within these.

A number of the points above were signaled by conversations between the author and retailers during the preparation of this report. Several retailers reported multiple daily visits by some customers and that attempts had been made to limit these customers’ access. Some of these conversations had proven positive while other customers had been angered by the efforts of staff. At least one owner had suggested that attempts might be made to identify vulnerable customers, e.g. those with mental health issues, with the view to having carers and / or parents support that person being declined service.

1.4.1 Discussion summary

The discussion has focused on current extant harms of synthetic cannabinoids in New Zealand. It commenced by noting the range of harms that had been reported domestically over the preceding three years. However, the point was made that the dynamism characterising the synthetic cannabinoid market (and more broadly that for all NPS) should likewise be applied to how these harms have been managed and especially the role that the legislative environment has played in this. It was proposed that there has been a reduction over time in exposure to the harms facing New Zealand consumers of synthetics. This is supported with reference to recently implemented legislation that has dramatically reduced retail outlets, advertising and actual product numbers. Similarly, on-going subsequently deployed public health surveillance has further reduced risks by identifying products having more than the stipulated low level of harm, with the result that these are then removed from the market. The most recent legislation aims at further risk reduction by raising manufacturing and supply standards. Industry support of these measures was also discussed.

Nonetheless there remain problems concerning the relationship between the regulations and how local authorities apply these. It appears that the spirit of The Act, i.e. that prohibition of synthetic products should be eschewed in favour of regulation—a harm reduction approach, has not been embraced by all parties. This is evidenced in the deployment of prescriptive LAPPS by some councils. Negative outcomes include increased consumer traffic to potentially lower quality outlets and increased internet sales. The latter is potentially problematic due to possible poor monitoring of customer access, especially under age, despite some examples of retail best practice. One possibility is that a greater effort on the part of The Authority be
attempted to communicate the regulations’ practicalities. A preference for greater flexibility and communication with The Authority was likewise signaled by some in the industry.

The need for minimum pricing was also discussed, with the suggestion that synthetic cannabinoid products should not be available at a lower price than raw cannabis. This reflects that likely at least 95% of consumers have previously used raw cannabis and that as yet it appears synthetic products are arguably more harmful than raw cannabis. Alternatively, some retailers recognise the value of attracting consumers away from potentially dangerous purveyors of illegal and poor quality cannabis. It seems at least some consumers may support this view.

**Part 2. Comparing Synthetic Cannabinoid Harms With Other Psychoactives**

Bearing in mind the flawed data set for synthetic cannabinoids, it nonetheless remains germane to attempt a comparison of their harms with those of other currently available psychoactives. Alcohol is an appropriate candidate for a first comparison.

2.1 Alcohol

![Harm Caused by Drugs](image)

Figure 7: Harm comparison between alcohol and other drugs*

*Source: Nutt et al. (2010)

While the example (*Figure 7*) does not represent the only or a final comparison, i.e. the exact order of drugs listed may be open to dispute and its source is a UK analysis (Nutt et al., 2010), it does offer an insight into alcohol’s potential for harm.

In New Zealand numerous reports and peer-reviewed articles have explored the harm associated with alcohol, including government and private sector publications. Given
the limited scope of the present report in this regard these will not be explored in great detail.

Probably the first and definitely most relevant point to note is that the considerable harms associated with alcohol accrue due significantly to its wide use. While alcohol has long been New Zealanders’ most popular drug, the 1989 liberalisation of the Sale of Liquor Act saw the number of licensed premises more than double from 6295 in 1990 to 14,183 by 2009 (Connor et al., 2011). The most recent Ministry of Health data available suggest that 80% of people aged over 15 years used alcohol in the previous year (Ministry of Health, 2013b). Further, that 19% were drinking at hazardous levels and that young people (18-24 years) were more likely indulge in hazardous drinking, e.g. 44% of male past-year drinkers and 26% of females. The Ministry observes that 3.9% of all health loss is due to alcohol (i.e. disability-adjusted life years).\(^\text{19}\) In terms of outright mortality, Connor and colleagues (2013) estimate that between 600-800 New Zealanders die each year from alcohol-related causes. For males more than half of these deaths (52%) involve injuries, with the figure for females being 25%. These authors also list 24 non-injury conditions alcohol impacts on, under 7 categories. Notably they also list benefits, something lacking in analyses of illegal drugs (e.g. Slack et al., 2008).

The above harms and others may be assessed by various means, for example using economic cost as the metric. This has been carried out by a Ministry of Health and ACC-commissioned report (Slack et al., 2009) that estimated alcohol-related costs of $4.94 billion and all other drugs-related costs of $1.58 billion, 76% and 24% of total costs respectively for alcohol vs all other drugs.

The Health Promotion Agency,\(^\text{20}\) a Crown entity established under the New Zealand Health and Disability Amendment Act (2012), records numerous statistics on alcohol harms and costs. These include:

- Between 18% and 35% of injury-based emergency department presentations are estimated to be alcohol-related, rising to between 60% and 70% during the weekend;
- 14% of the population are predicted to meet criteria for an alcohol-related substance use disorder at some time in their lives;
- Police data noting alcohol is involved in:
  - 30% of all police apprehensions;
  - 50% of violent crimes;
  - over 300 offences committed each day;
  - 52 intoxicated individuals either driven home or detained in police custody daily;
- regarding drink driving (2012 figures), driver alcohol contributed to:
  - 73 fatal crashes;
  - 331 serious injury crashes;
  - 933 minor injury crashes;


Above resulted in, per annum (2012 figures):
- 93 deaths;
- 454 serious injuries;
- 1,331 minor injuries.

The economic burden imposed by alcohol is consistent with analyses of its relative harm compared to other drugs in terms of risk, despite it being legally available. For example, Sellman and colleagues (2009) assessed alcohol according to the criteria used to determine risk and harm for controlled drugs under the Misuse of Drugs Act (1975). By their calculation alcohol would be categorised as a ‘Class B1’ drug, with their assessment suggesting alcohol is at least as dangerous as the comparator they used, γ-hydroxybutyric acid (GHB).

With reference to the present analysis of synthetic cannabinoids, the considerable harm deriving from alcohol is well recognised by the Ministry of Health. Thus it is notable that in determining its threshold for the metric of a low level of risk or harm, the Ministry comments that if alcohol was to be assessed using the modified Freiburg framework developed for assessing NPS and specifically synthetic cannabinoids, it would exceed the acceptable limit of harm and therefore be banned:

> It is interesting to note that the data we hold for alcohol consumption within the population has similar problems to those identified for psychoactive substances. However, based on the limited data available, if alcohol in general was placed within the psychoactive products risk assessment framework the reported adverse effects of acute alcohol use would produce a risk score that is greater than 2 i.e. it poses more than a low risk of harm.
> —Ministry of Health (2013c:6)

There is no doubt, therefore, that despite its legal status alcohol is New Zealand’s most damaging drug by a significant margin. It is also interesting to note that in the above passage the Ministry refers to the “limited data available” regarding alcohol. Based on the data presented above, one might argue that there is in fact almost a surfeit of available data on alcohol harms.

### 2.2 Raw Cannabis

While a search of the Health Promotion Agency’s (HPA) website using the term ‘alcohol harms’ returns numerous responses, a search using the term ‘cannabis harms’ produces no results. This reflects the fact that the HPA has a mandate only for substances and activities it is funded for, e.g. drugs such as alcohol and tobacco, and gambling (personal communication between the author and Sue Paton, Principal Advisor Addictions, HPA, 18 March 2014). Nonetheless, cannabis is well recognised for a range of harms, which are no respecter of legal status. Again, exploring these in significant depth is beyond the scope of the present report. Thus a brief summary follows.

Much of the research assessing cannabis harms is directed at clinical problems, e.g. psychological, physical and injury-related outcomes. One point made regularly is that unlike most recreational drugs, cannabis is remarkably safe if one uses mortality as the metric: there has never been a recorded death attributed directly to cannabis (e.g.
see Calabrie et al., 2011). There are numerous other health issues arising from its use, however, including elevated risk of mental ill-health for some individuals commencing use in their teens, respiratory damage, cognitive impairment and elevated risks associated with use while operating machinery. Significantly Caspi and colleagues (2005) suggest that up to 25% of the population may be at greater risk of negative mental health outcomes later in life if regular adolescent uptake of cannabis occurs. Finally, while often neglected, as with all illegal drugs, users of cannabis also face harms generated from the enforcement of anti-drug laws, something that in the cannabis’ case, has been argued as disproportional to the harms associated with use per se (Noller, 2008).

As with alcohol, there have been attempts at framing cannabis harms in social and economic contexts in New Zealand. The report noted above regarding alcohol (Slack et al., 2009) is one of these, as is Slack and colleagues’ (2008) Drug Harm Index. As both effectively draw on the same data, discussion will be limited to the latter, along with publications referencing it.

While many less people in New Zealand use cannabis compared with alcohol, e.g. use last year and still using—15% (Ministry of Health, 2010), the country has one of the highest prevalence rates in the developed world, ranked seventh out of all countries, with only the Czech Republic reporting higher use among developed nations (UNODC, 2011). In noting this prevalence, however, one must understand it is well accepted that rates of reported illegal drug use are typically less than actual rates, due to surveyed populations not wishing to identify their use. It is likely, therefore, that upwards of 20% of New Zealanders are regular cannabis users, i.e. approximately 400,000 people aged over 15 years (Noller, 2008). For this reason alone there will be significant harm-related costs, which Slack et al. (2008) estimate to be $431 million of the $1.31 billion for all illegal drugs (33%), at 2006. While this amount is less than 9% of what Slack and colleagues (2009) estimated alcohol cost New Zealand, even this costing of harm has been objected to as inaccurate and exaggerated. For example, critics note that much of the cost comprises drug production and enforcement (see NORML, 2014).

In an earlier analysis Ritter (2008), although acknowledging the complexity of determining such costs, nonetheless raises concerns about data integrity presented by Slack and colleagues (2008). She notes problems with the latter’s reporting of data determining levels of use and, where these might be set, the extent of use, frequency and what other drugs might also be contributing to harm, a matter raised in the present report with regard to the harms from synthetics.

A final point concerning Slack and colleagues’ analysis (2008) involves the neglect of considering that cannabis consumption (as with other drugs) may also have some benefits. In cannabis’ case this is especially germane given the increasing global awareness of its medicinal properties.21

In summary, therefore, established cannabis harms are mitigated by less use than for alcohol (last year use, 15%-20% vs 80% of those aged 15+) and the lack of any direct

21 Articles discussing medicinal cannabis, both scholarly and non-peer reviewed are too numerous to be meaningfully discussed in this report. The reader is directed to the following link for a brief review: http://en.wikipedia.org/wiki/Medical_cannabis
mortality associated with cannabis. Moreover, even if accepting the problematic data discussed (i.e. Slack et al., 2008), by that analysis the harms of cannabis are less than 9% of those attributed to alcohol by the same authors.

Recommendations

The following recommendations are of two general categories. The first concerns how the industry might manage others’ perceptions of it, i.e. in terms of how harms produced by the industry’s products may be described to interested parties beyond the industry, such as media, local bodies and interest groups representing vulnerable populations, e.g. the treatment, mental health and youth health sectors. The second category of recommendations focuses on issues or opportunities relating directly to the industry’s activities, for example the possibilities that might arise from altering current products or from the development of new ones.

1 Discussion of harms: It is recommended that when discussing synthetic cannabinoid harms, or responding to concerns about NPS products and specifically synthetic cannabinoids, that the industry accepts that its products do carry some harm. All drugs have negative side effects. In the case of synthetic cannabinoid products, there is a clear body of evidence indicating a range of harms. It would be disingenuous to suggest otherwise.

Instead, industry representatives, for example The STAR Trust, could focus on how exposure to harms has consistently reduced since the inception of the NPS market. While this has been driven by legislation, there is clear evidence of a willingness on the part of industry to engage with this process. This has been recognised in Government publications, issues papers and related documentation.

2 Industry should continue to emphasise its legality and legitimacy. Spokespeople for the industry should familiarise themselves with legislative rationale underpinning the safety of approved products. This particularly includes the Freiburg framework and how this identifies what a low level of harm is. An understanding of the ‘natural history’ of the evolution of NPS / synthetic cannabinoid harms and exposure to them should also be developed. Emphasis should be placed on the steady reduction of exposure to these over time, as the risk assessment and management tools of Government and industry have matured.

3 The discussion of the harm threshold or low level of harm might usefully be linked to the greater harms of alcohol. This should be done with specific reference to the Ministry of Health’s (2013c:6) Safety Assessment of Psychoactive Products, along with drawing people’s attention to sites highlighting alcohol harms, e.g. the HPA.

4 Consistent with point 1 (above), industry (i.e. The STAR Trust) should give serious consideration to redeveloping its website. Particular attention
could be paid to providing online help and advice for consumers who may be experiencing negative effects of use, for example by providing tools similar to those accessible on DB Breweries’ Our Responsibility page, that links to the cheers.org.nz site (see supra note 17). See also the HPA link to alcohol.org.nz. This information provision could also extend to the websites of businesses who are PITA members.

5 The industry should aim to build networks with all non-industry stakeholders such as local bodies and the health sector, especially acute health services and mental health organisations. Though difficult, an emphasis should be placed on transparency and facilitation of understanding that the industry recognises there are harms associated with its products, that it is genuinely interested in limiting these through best practice and that as an industry, it has legislative backing.

6 The industry and The Authority should give consideration to adopting a minimum pricing regime. This is based on evidence that the vast majority of synthetic cannabinoid product consumers have previously consumed raw cannabis. The approximate price per gram of raw cannabis, i.e. $12 / gram, could be considered relevant for synthetic products, thereby avoiding a potential expansion of consumption due to a lower price for ostensibly a similar product, and arguably one with greater harms.

7 The industry and The Authority should consider increasing compliance and surveillance of retailers, including internet sales, particularly with regard to age restrictions.

8 The industry should continue to support relevant research and particularly encourage peer-reviewed publications related to its activities. If funding for this is derived from members of PITA, these organisations / businesses should be educated about the value of them contributing to this activity.

9 The Industry should consider the value of developing non-recreational drugs that might be used to ameliorate the negative effects of its recreational products. An example might be drugs aimed at attenuating psychosis, anxiety and withdrawal symptoms associated with synthetic cannabinoid products. Consideration should also be given to revisiting the inclusion of CBD-type analogues in any subsequent products.

http://www.alcohol.org.nz/?gclid=CMfY0YPlmr0CFUchpQod308AzA
References


Appendices

Risk Assessment - Effect and Exposure

For the purpose of this risk assessment the paper by Maren Hermanns-Clausen et al contained in the literature review is particularly useful. This paper, published by a poisons information centre in Freiburg (Germany), sets out a poisoning scoring system based on the nature and severity of the adverse effects. The scoring system classifies adverse effects into minor, moderate or severe categories.

The Freiburg scoring system has utility for making risk assessments of psychoactive products. However, the risk scoring framework described in the paper needs to be adapted to take into account the advice received from the Interim Psychoactive Substances Expert Advisory Committee (IPSEAC) and the information available within the New Zealand data set. This data set consists of reports of adverse events and effects collected by the National Poisons Centre (NPC), the New Zealand Pharmacovigilance Centre (NZPhVC) and some hospital accident and emergency units.

The IPSEAC has recommended that for risk assessment purposes, psychoactive products should be treated in a similar way as pharmaceuticals intended for acute intermittent use. The Freiburg risk assessment framework has therefore been adjusted to ensure acute effects are scored differently from adverse effects associated with chronic use. The IPSEAC advice aligns with the risk management approach taken by both regulators and society towards alcohol, the most commonly used psychoactive substance.01/10/2013 4

The data set used to inform the risk assessment consists of the adverse effects for psychoactive products reported to the National Poisons Centre (NPC) and the New Zealand Pharmacovigilance Centre (NZPhVC) over the past 6 months and data from a subset of hospital accident and emergency units for the month of July 2013.

Each record describes an event e.g. a visit to a medical facility, secondary to concerns about one or more adverse effects associated with use of a psychoactive product. The risk assessment framework examines each reported adverse effect for best fit with the criteria for the poisoning severity score set out in the Hermanns-Clausen paper and scores the effect as 1, 2 or 3 depending on whether the effect is assessed as minor, moderate or severe.

A number of the adverse events reported to the NPC are associated with withdrawal or stopping use of a product after chronic exposure. Experience with pharmaceuticals indicates that reports of withdrawal effects can be surrogate markers for addiction to a product. As a result of this information, withdrawal effects associated with stopping a psychoactive product after prolonged use have been included in the risk assessment
framework. Effects associated with chronic use/withdrawal have been scored by severity (score 1-3) using the same scoring system as set out in the Hermanns-Clausen paper.

**Exposure data**
Sales data, when provided for a product, will be used as a surrogate for numbers of persons exposed to the product. These data form an exposure denominator that can be used to standardise the risk assessment framework and allow the Authority to compare report rates for adverse effects and put them into perspective.

In pharmaceutical assessment, products available for sale over the counter are considered by regulators to be low risk products. One assessment point used in determining risk for pharmaceuticals is to assess whether exposure to the product in a clinical trial, or in community use, is associated with reporting of an adverse effect at a rate of more or less often than 1 in 10,000 users. Pharmaceutical experience supports the use of utilising 1 in 10,000 users exposed as a threshold for assessing overall risk for determining low vs. higher risk products.

It is important to note that all medicines, even low risk products, can cause harm and have a potential to cause severe and serious adverse events including death. These serious events can occur due to allergy, idiosyncratic response to the active ingredient, interaction with other medicines, overdose or misuse. The situation for psychoactive products will be no different.

**Adjusting for effect and exposure**
In order to make a pharmaceutical-type assessment for psychoactive products obtaining sales data for products, as a surrogate for numbers of persons exposed to the product, is important. In order to use these data the Authority has developed a series of effect and exposure multipliers or adjusters to standardise the risk assessment.

The Authority has determined that where the sales volume of a product is less than 10,000 units, an exposure multiplier of 2 will be used on the risk score in each risk category of the framework (i.e. for each minor, moderate, severe or chronic effect reported).

Where more than 10,000 units of a product have been sold and the number of minor events reported is disproportionate to the sales volume, then an exposure multiplier of 2 or 3, depending on the scale of disproportion, will be applied to the individual score for each implicated risk category (i.e. for each minor, moderate, severe or chronic effect reported). A working example of this approach would be: if 20,000 units are sold and 4 adverse events are reported then the risk score multiplier for each implicated risk category will be 2; if 6 or more adverse events are reported for sale of 20,000 units the risk score multiplier at each implicated risk category will be 3.

A similar proportionate approach to risk scoring will be applied to the severity of an adverse effect. Where moderate, serious or chronic adverse effects are reported, each effect category will be scored separately irrespective of the exposure data provided e.g. 2 minor adverse effect reports in a population of 20,000 users would give a risk score of 1, however, 2 serious adverse effect reports in the same population would create a score of 6.
Appendix 2: Letter requesting sales data from New Zealand companies marketing synthetic cannabinoid products.

27.1.14

Address

Re recent email from Star Trust concerning harm evaluation of synthetic cannabinoids in New Zealand, and a request for information

Dear Mr

I am following up on an email I understand you recently received from Angela McInerney, Research Manager with the Star Trust.

As Ms McInerney notes in her email, as the industry body representing the interests of synthetic cannabinoid manufacturers, wholesalers and retailers in Aotearoa, the Star Trust has engaged me to make a comprehensive evaluation of the harms associated with synthetic cannabinoid use in New Zealand. This assessment will in part compare synthetic cannabinoids with other drugs, particularly alcohol, which as we know is an accepted social tonic. The harms associated with some illegal recreational drugs, for example cannabis, ecstasy and opioids, may also be investigated for comparison.

To achieve the study’s aims, a range of data is sought. These include data from academic and formal studies, as well as from the New Zealand treatment and health sectors, e.g. hospital ED admissions, the AOD Help-Line and the National Poisons Centre, and the Ministry of Health. Some ‘unofficial’ data are also of interest, for example media stories reporting on events associated with consuming synthetic cannabinoid products.

However, a further important stream of data concerns levels of consumption. While it is difficult to accurately determine per capita consumption, i.e. the level of use per person and numbers of people consuming, it is possible to get some sense of how many units of products are being distributed, by drawing on industry figures from significant businesses.

It is for the above reason that I am contacting you. I am aware that you may not wish to discuss your own organisation’s information in detail. If possible, I would like to call you to discuss what information you are willing to share and under what conditions.

For your information, I invite you to visit my website: www.geoffnoller.com to reassure yourself of my qualifications and experience in this matter. Alternatively, you may wish to contact Grant Hall, of the Star Trust, on +6421900728 or email at grant@thestartrust.org.

I look forward to hearing from you via email or phone (as below) regarding my request to discuss these matters further, and thank you in advance.

Kind regards

Dr Geoff Noller
Substance Use and Policy Analysis
Tel. 03 471 0340
Mob. 021 471 042
Appendix 3: Email to GN from Stargate International pharmacologist James Williamson, regarding withdrawal effects of synthetic cannabinoid products; December 9 2013

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Sorry for slow reply been busy will try reply to your points quickly

- yes sometimes there does seem to be an extended period of withdrawal from these synthetic cannabinoids, I believe there may be several factors involved

  (i) the cannabinoid compounds being used now have just gotten stronger and stronger as older ones have been banned and replaced by newer ones, many of them now are similar potency to things like fentanyl or triazolam as well as having similarly short duration - so this means the withdrawals can be quite intense and prolonged compared to regular cannabis withdrawal, as the cannabinoid receptors in the brain are all downregulated due to tachyphylaxis and need time to regenerate. This doesn't happen to nearly the same extent with regular cannabis as THC is a partial agonist not a full agonist so has a lower ceiling level regardless of how much you smoke, and therefore is not capable of causing the same degree of tachyphylaxis as these potent full agonists.

  (ii) despite having short duration these synthetic cannabinoids are all very fat soluble and many of them probably don't get broken down quickly in the body, so they will build up in body fat stores especially with prolonged use over time. What I suspect may be happening is when people have acute withdrawal this completely kills their appetite for a few days, maybe makes them a bit nauseous too, and so they suddenly start burning body fat stores for energy and this releases some of the stored drug (you see this sometimes with other fat soluble drugs like benzos). So this probably relieves the initial symptoms a bit but then stretches out the withdrawal process much more, especially in people who have stopped after using heavily for some time, rather than if someone was just withdrawing from a single short binge or whatever.

We have identified partial agonists in the course of our research but not really any that would have really good characteristics as a substitute drug for recovery, they are all too short lasting and you generally want a longer lasting drug to wean people off short lasting drugs. Also of course to be used as a substitute in a medical setting it would need to be licensed as a medicine and prescribed by a doctor which is a bit outside our current product range...

Good old cannabis itself would probably be the best option in a perfect world, a nice high-CBD strain with maximum antipsychotic efficacy. So theoretically something like that under the tongue spray of THC/CBD (called Sativex I think?) could be an option, seeing as it is already approved for MS (not that it gets prescribed much from what I hear, as it isn’t usually subsidised and is a lot more expensive than illegal cannabis!) Nabilone is another option, though I’m not sure if thats even available here. But yeah I think the longer duration of these would make them much more suitable as a substitute drug.
INDUSTRY SUBMISSION REGARDING THE ESTABLISHMENT OF A LOCAL APPROVED PRODUCT POLICY

BACKGROUND

1. The STAR Trust is an industry body that represents the majority of retailers licensed under the Psychoactive Substances Act 2013 [PSA]. The STAR Trust is also a non-profit NGO that advocates for drug policy reform and funds research into the use of psychoactives as medicine.

2. The Psychoactive Industry Training Association [PITA] was established in September 2013 and is managed by The STAR Trust. Approximately 80% of licensed retailers are members of PITA and have formally made a commitment to a Code of Conduct that sets a standard above that required by the PSA. PITA audits industry members to ensure compliance with the Code of Conduct.

3. Parliament enacted the PSA as a public health initiative. The PSA aims to create a strictly regulated market for psychoactive products that are proven to pose no more than a low risk of harm, and bans the sale and possession of psychoactive products which are not proven to be low risk.

4. The PSA commenced in July this year and resulted in a 95% reduction of retail outlets and strict controls around how products were created and sold. The few remaining retailers are committed to the success of the PSA and understand that during this ‘interim’ period some members of the public may still have concerns about what a regulated marketplace means for local communities.

5. The PSA empowers territorial authorities to create Local Approved Product Policies [LAPPs]. The STAR Trust, on behalf of licensed retailers, is engaged with territorial authorities across NZ to provide assistance in the development of fair and appropriate LAPPs. This submission is designed to assist territorial authorities in that process.

RETAIL RESTRICTIONS AND REQUIREMENTS UNDER THE PSA

6. The PSA provides for comprehensive regulation of the retail of approved psychoactive products, and a LAPP is one of a number of mechanisms in the Act for this purpose. Understanding the other mechanisms in the Act will assist a territorial authority in determining whether they need a LAPP and the proper scope of a LAPP if one is made. In particular, a territorial authority should be aware of the:

(a) requirement that products be approved;
(b) retail restrictions imposed directly by the Act;
(c) retail restrictions that can be imposed through regulation; and
(d) retail restrictions that can be imposed by an LAPP.

7. Each of these is explained below.
Products must pose no more than a low risk of harm

8. One of the key functions of the PSA is to require that all psychoactive products sold in New Zealand must be approved. A product cannot be approved unless the Psychoactive Substances Authority [the Authority] is satisfied that the product poses no more than a low risk of harm. Further, if a product is approved and the Authority later considers that the product poses more than a low risk of harm, then they can revoke their approval.

Retail restrictions imposed directly by the PSA

9. The PSA imposes some retail restrictions directly. In particular, the following retail restrictions are imposed directly by the PSA, and apply nationwide:

(a) Retailers must be licensed, and their licenses can be cancelled. All retailers of approved products must hold a license to sell psychoactive products issued by the Authority. Under section 16 of the Act the Authority can only issue a licence to an individual that is a fit and proper person, or to a body corporate that is of good repute. Section 22 of the Act empowers the Authority to cancel or suspend a license if the licence-holder fails to comply with the Act, or has ceased to be a fit and proper person, or of good repute.

(b) Approved products cannot be sold in dairies, convenience stores, supermarkets, liquor stores, temporary stores, or petrol stations. Section 52 of the Act provides prohibitions and restrictions on the place of sale of approved products. The Act prohibits the sale of approved products from: dairies; convenience stores; supermarkets or grocery stores; petrol stations or places for servicing vehicles; premises that are not fixed permanent structures (such as a tents, marquees or stalls); or vehicles.

(c) There are strict restrictions on advertising approved products, including that advertising cannot be easily visible or audible outside a retail premise. Section 56 of the Act contains restrictions and requirements relating to the advertising of approved products. Advertising of approved products is confined only to inside the premises of the retailer, and the advertising must not be easily visible or audible from outside the premises. Advertising must be limited to objective information, and cannot convey that the product is safe or be designed to appeal to minors. Approved products cannot be advertised on television, radio, the internet, or in a newspaper or periodical.

(d) Approved products cannot be sold to, or by, people under 18. Section 49 of the Act prohibits retailers from selling approved products to a person under 18 years old. Further, section 51 prohibits retailers from employing anyone under 18 to sell approved products.

(e) Approved products cannot be offered for free, and cannot be sold as part of a promotion. Section 54 of the Act prohibits retailers from providing an approved product free of charge for the purpose of their retail business (such as in a promotion). Section 54 further prohibits retailers from offering any gift, cash rebate or any contest, lottery or game to the purchaser of approved products.
Restrictions that can be imposed by regulations

10. The PSA also allows the Government to create regulations to further restrict and control the retail of approved products. Under section 101 of the PSA, these regulations can cover:
   (a) Place-of-sale restrictions (in addition to the current restrictions in the Act);
   (b) Labelling restrictions or requirements (a mandatory health warning must be included in the regulations);
   (c) Advertising restrictions (in addition to the current restrictions in the Act);
   (d) Packaging restrictions or requirements;
   (e) Signage requirements;
   (f) Internet sale restrictions and requirements;
   (g) Quantity, dosage, and serving restrictions or requirements; and
   (h) Storage, display and disposal restriction or requirements.

11. There are some regulations that the Authority must create to bring the PSA into full effect. Territorial authorities can expect that regulations will be made in early 2014.

LOCAL APPROVED PRODUCT POLICIES

Restrictions that can be created by LAPPs

12. The PSA empowers territorial authorities to create LAPPs. Section 68 of the Act provides that a LAPP may specify the location of premises from which approved products can be sold, by reference to one or more of:
   (a) broad areas within the district;
   (b) proximity to other premises from which approved products are sold within the district; or
   (c) proximity to premises or facilities of a particular kind or kinds within the district (for example, kindergartens, early childhood centres, schools, places of worship, or other community facilities).

13. The PSA does not empower territorial authorities to use LAPPs to:
   (a) create other forms of retail regulations;
   (b) prohibit, or effectively prohibit, the retail of approved psychoactive products in their district; or
   (c) regulate internet sales within a district.

14. The STAR Trust submits that LAPPs can be legitimately used for planning or zoning purposes, to ensure that retail outlets are not too close to each other, and to ensure that they are not too close to “sensitive” sites such as schools. The STAR Trust believes that any other purpose would be inconsistent with the requirements of the PSA.

Matters to take into account in developing a LAPP

15. The STAR Trust believes that, in developing LAPPs, territorial authorities should take into account that:
   (a) The products being sold pose no more than a low risk of harm.
There are very tight retail restrictions in the PSA, and further restrictions are likely to be applied through regulations which are yet to be created.

The PSA is only new, and regulations should not be created based on evidence or anecdote about the pre-PSA period.

16. Taking those matters into account, the STAR Trust believes that these principles should guide territorial authorities in developing LAPPs:

(a) Territorial authorities have an interest in upholding the integrity of the PSA as a public health initiative. This will minimise the illicit trade of drugs and ensure responsible and regulated retailers within your district.

(b) The interests of current licenced retailers (who must be considered of good character or good repute) should be taken into account. In particular, retailers should not be unreasonably expected to move location during the interim period. The STAR Trust submits that where it is proposed that a current retailer must move, that there be a decision making process which involves an independent adjudicator which can make an assessment of what is fair and reasonable in the circumstances.

(c) Restrictions on retail outlets being in proximity to other premises (such as sensitive sites or other retailers) should not be any harsher than policies affecting the location of alcohol or tobacco outlets. There would be no rational basis for a harsher policy to be applied to psychoactive products. This is especially so given that, unlike for liquor stores, there can be no advertising of psychoactive products outside a store. The STAR Trust submits that it would be appropriate for retailers to be no less than 50 metres away from an agreed ‘sensitive’ community site.

(d) Territorial authorities may wish to consider developing relationships with responsible retailers in their districts, and promoting the enforcement of the requirements in the PSA. Partnering with the industry and the Authority to ensure that retailers uphold the requirements in the PSA, including the “good character” requirement, may be a more effective mechanism for protecting the public health of a district than a blunt LAPP.

17. The STAR Trust remains available to territorial authorities to discuss this submission, and other matters to do with the PSA within your area.

Sincerely,

GRANT HALL

ATTACHED - CODE OF CONDUCT