The new psychoactive substances regime in New Zealand: a different approach to regulation

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Abstract:

The New Zealand Government has proposed a new psychoactive substances regime, which will place the onus onto manufacturers to prove their products pose a low risk of harm, prior to receiving approval which allows them to be legally manufactured and sold. This is an innovative and unique development in the regulation of emerging psychoactive substances, and offers an alternative response to prohibition. The details of the new regime and how it will operate are now emerging, and this offers an opportunity to critically explore some of the issues related to the proposed new regime and to speculate on some of the outcomes. This paper brings together a group of New Zealand based researchers from a range of disciplines with experience of legal high research to discuss this innovative new regime.

Keywords: New psychoactive substances regime, regulation, legal highs, harm reduction, policy
Introduction

The last 15 years has seen the increasing availability of a new type of psychoactive substances known as ‘legal highs’ (Cohen and Butler, 2011, Sheridan et al., 2007, Winstock and Ramsey, 2010). Their use and popularity has rapidly spread through mainly youth and young adult communities, aided by the internet and the rapidity with which such trends are communicated and New Zealand has been particularly affected by this phenomenon (Sheridan et al., 2007, Wilkins et al., 2007, Wilkins and Sweetsur, 2012, Wilkins et al., 2008). As a geographically isolated country, New Zealand is less connected to global drug supplies of illicit substances such as cocaine and heroin. Furthermore, drugs such as ecstasy are expensive and low purity, and in this context there has been a high demands for substitute drugs (Wilkins et al., 2012).

The New Zealand government recently announced its intent to develop a pre-market approval regulatory regime for ‘legal highs’, known as the new psychoactive substances regime (NPSR) (Dunne, 2012). Manufacturers and distributors seeking to legally sell new psychoactive substances will be required to gain approval from a regulator in advance of sale by demonstrating the product poses a ‘low risk of harm’ (Treasury, 2011). This pre-market approval regime will essentially ‘reverse the onus of proof’ from the government which has to establish harm to determine whether further controls are warranted, to the manufacturers and importers who will have to demonstrate their products pose a low risk of harm, in advance of legally selling them (Ministry of Health, 2012, Treasury, 2011).

The proposed new regime is the first of its kind worldwide attempting to create a legal regulated market for new psychoactive substances (Sheridan et al., 2012). Once established, the new psychoactive substances regime will create the first new legal drug sector in New Zealand since the establishment of the alcohol and tobacco industries. The proposed regime is a radical departure from the traditional responses to regulating the availability of psychoactive drugs in New Zealand (and indeed most of the world) which are largely based on prohibition. It is consistent with a harm reduction philosophy and in line with New Zealand’s drug policy which “aims to reduce the effects of harmful substance use through a balance of measures” which includes controlling or limiting the availability of drugs (supply control) (Ministerial Committee on Drug Policy, 2007). This paper seeks to outline how the new regime will work based on material released by the Government to date and provide a critical discussion of these proposals and related issues.
Background

The development of the NPSR has been presented as a solution to the problem of an unregulated industry selling unscheduled psychoactive substances in an unregulated market. This problem first emerged in New Zealand the early 2000s, with legal ‘party pills’ containing combinations of benzylpiperazine (BZP) and trifluoromethylphenylpiperazine (TFMPP). In 2004, the problem of determining harms associated with the use of BZP was referred to the Government’s Expert Advisory Committee on Drugs (EACD), a statutory body established to provide advice to Government about the scheduling of psychoactive drugs under the Misuse of Drugs Act (MODA). At that time, the EACD concluded there was insufficient research about BZP to determine whether it posed a risk (Expert Advisory Committee on Drugs, 2004).

During this time the manufacture and sale of BZP and related substances remained unregulated in New Zealand, with products sold to any age group from a range of retail outlets, including internet websites, convenience stores, premises selling alcohol and tobacco, and ‘drug paraphernalia’ and ‘adult’ stores (Ministry of Health, 2012, New Zealand Law Commission, 2011). The BZP market grew quickly and at its height in the mid-2000s the BZP party pill industry in New Zealand was estimated to have sold as many as 200,000 party pills per month and earn retail sales worth $25-$35 million dollars per year (NZ$) (Dawkins, 2008, Ministry of Health, 2012, New Zealand Law Commission, 2011). A 2006 national household survey of BZP use in New Zealand found 15% of the population aged 13-45 years old, including 40% of males aged 18-24 years old, had had used a BZP legal high in the previous 12 months (Wilkins et al., 2007). It has been estimated that between 80-120 different BZP/TFMPP products were available during this time (Ministry of Health, 2012).

The wide availability of these products generated public concern, particularly in regard to use by school children, and research found their use was associated with a number of admissions to hospital emergency departments (Gee et al., 2005).

Following EACD recommendations in 2004, to consider introducing a lower class category of the MODA which could allow low-risk psychoactive substances be legally sold subject to market restrictions (Expert Advisory Committee on Drugs, 2004), an attempt was made in 2005 to provide greater regulation of the legal BZP market by developing the ‘restricted substances’ regime via the Misuse of Drugs Act Amendment (MODAA) (Anderton, 2004) although this was not utilised. By 2007, a review by the EACD of a mounting body of evidence about the use, and harms of BZP and related substances (see (Alansari and
Hamilton, 2006, Butler and Sheridan, 2007, Nicholson, 2006, Wilkins et al., 2007, Wilkins et al., 2008) concluded they posed a ‘moderate risk’ of harm (Expert Advisory Committee on Drugs, 2006). This led to it being prohibited in 2008. However, BZP party pills were soon replaced in the marketplace by a series of unregulated party pills containing other psychoactive compounds, followed by unregulated synthetic cannabinoids with product names such as Spice and Kronic (Expert Advisory Committee on Drugs, 2009). These new psychoactive substances were being sold without regulatory control over their manufacture/sale and consequently posed a potential risk to consumers (Wilkins, 2011). Government was also required to identify and prove whether these new substances were harmful in order to prohibit them (Ministry of Health, 2012). This was difficult, as research about the risks of the new or obscure substances was often scarce or non-existent, time consuming and financially costly (identifying their ingredients required detailed chemical analysis).

In the absence of robust evidence outlining risk of harm the Minister was able to issue a Temporary Class Drug Notice under the Misuse of Drugs Act 1975. A Temporary Class Drug Notice may restrict any substance that the Minister is satisfied may pose a risk of harm to individuals, or to society. However, Ministry of Health (MOH) rejected 12 month temporary bans as a sustainable solution, as bans were unlikely to provide sufficient time to evaluate a new drug (Treasury, 2011). The MOH also pointed out that temporary bans did not remove the onus on the Government to identify new psychoactive substances and related harms, and to take appropriate actions (Office of the Associate Minister of Health and Cabinet Social Policy Committee, 2012b).

The development of the new psychoactive substances regime

A pre-market approval regime for new psychoactive substances has been developed to cover new substances, excluding psychoactive substances already covered by their own legalisation. These include alcohol and tobacco, psychoactive medicines covered by the Medicines Act and in the case of caffeine, the Food Act. The proposed definition of a psychoactive substance is a substance which has the primary purpose of being administered or taken in order to induce a psychoactive effect (Office of the Associate Minister of Health and Cabinet Social Policy Committee, 2012a). This would include all party pills and other legal highs. Substances which can be shown to possess ‘low harm’ will be approved for legal
sale subject to retail restrictions. All unapproved, new or existing ‘legal highs’ would automatically become illegal once the regime comes into existence, but there is a proposed provision for a transition period to allow the continued sale of legal highs that have been on the market for 6 months prior to commencement provided they apply to the regulator for approval following commencement. Government agree the new regime, and in particular the pre-approval process, should be operated by a separate regulatory authority within the MOH (Ministry of Health, 2012; Office of the Associate Minister of Health & Cabinet Social Policy Committee, 2012a; Treasury, 2011), and that regulatory costs of the new regime, such as administration, expert advice, enforcement and post-market auditing should be entirely recovered from the application and licence fees charged to industry sponsors (Ministry of Health, 2012; Office of the Associate Minister of Health & Cabinet Social Policy Committee, 2012a; Treasury, 2011). The proposed new psychoactive substances regime is consistent with a harm minimisation approach to legal highs, rather than eliminating use altogether.

The aim is to develop a ‘regime capable of dealing with the rapidly evolving market in new drugs, and balancing risk of harm to individuals and society with the demand for access to such drugs’ (Treasury, 2011).

An NPSR goes some way to legitimising the industry and its pursuit of profit. The industry sponsor of a product will be required to provide the regulator with toxicology and human clinical trial data on the health risk of their product (Ministry of Health, 2012, p.11). This is likely to involve data on acute toxicity, repeat dose toxicity, genotoxicity and observations from human clinical trials (Ministry of Health, 2012). The MOH estimates the required product testing would cost between $1-2 million per product and take between 6-12 months to complete (Ministry of Health, 2012), and anticipates that ‘at most 10 products’ would be submitted for approval in the first 1-2 years of the regime. In the most recent policy analysis the MOH calculates a fee of $180,000 per application would be required to cover the total cost of the regulatory agency based on a projected 24 applications in the first four years (Office of the Associate Minister of Health and Cabinet Social Policy Committee, 2012b, p7).

The MOH and Government appear to be committed to an independent and objective approval process which has no imposed limits on the number of products which can be approved (i.e. ‘products that meet the approval criteria will be approved’ (Dunne, 2012) and so it is conceivable that more than 24 products will be approved over the first four years of the regime, particularly if some new applications can draw on the results of previous testing, which seems likely.
In October 2012, the Government announced the details of the retail restrictions they intend to impose on approved products (Office of the Associate Minister of Health and Cabinet Social Policy Committee, 2012b). These include a minimum purchase age aligned with the alcohol purchase age (i.e. currently 18 years old), no advertising except at the point of sale, no promotion that is particularly appealing to children, advertising confined to objective product information, no sponsorship of products, no incentives to encourage purchase (e.g. free samples), and no promotion which conveys that a product is safe (Office of the Associate Minister of Health and Cabinet Social Policy Committee, 2012b). Advertising of products is to be limited to the ‘point of sale, either within the premises where they are sold or supplied, or on the internet sites from which they are sold or supplied” (Office of the Associate Minister of Health and Cabinet Social Policy Committee, 2012b). The sale of approved new psychoactive substances will also be prohibited from some types of retail outlets, including service stations, convenience stores, and places where children gather, such as schools and sports facilities (Office of the Associate Minister of Health and Cabinet Social Policy Committee, 2012b). More controversially, Government has indicated it would remove the prohibition of sales from premises which have a licence to sell takeaway alcohol (off-licence), but continue to prohibit their sale from outlets with a licence to sell alcohol which is consumed on premises (on-licence) (Office of the Associate Minister of Health and Cabinet Social Policy Committee, 2012b). The rationale for this is that people buying from on-licenced premises are more likely to be under the influence of alcohol, whereas those purchasing from off-licence outlets may be less likely to have commenced drinking, and therefore able to make more sensible decisions. Furthermore, the Government contends that alcohol off-licence premises have systems in place to verify age (Office of the Associate Minister of Health and Cabinet Social Policy Committee, 2012b).

The Government also recently announced that it will not impose an excise tax or minimum price on approved new psychoactive products, as there is insufficient information to model the extent to which demand would be affected by a price increase (Ministry of Health, 2012, Office of the Associate Minister of Health and Cabinet Social Policy Committee, 2012b). They propose to monitor the situation and review it in five years’ time as part of the general review of the regime, or earlier if circumstances dictate.

Discussion
The proposed NPSR is an exciting development in the search for a means to control these new substances, and has previously been described by two of the authors as potentially “fit for purpose” (Sheridan et al., 2012). More recently, the detail of the regime has emerged, and this allows us the opportunity to critique and appraise this detail, explore some of the potential consequences and discuss some of the uncertainties which remain. The Government has approved the details of the proposed new regime and is currently in the process of drafting a legislative Bill based on these proposals. The draft Bill will be reviewed by a Parliamentary Select Committee and will be debated in Parliament before being passed into law. Consequently, some of the details of the proposal may change in the preceding six months or so. Our discussion here is of the details of what is currently proposed in the draft Bill.

The proposed regime creates a category of ‘low harm’ psychoactive substances; however, there is no accepted definition of low-harm against which to assess these products (Ministry of Health, 2012). Currently, psychoactive substances are classified under either the Misuse of Drugs Act (e.g. BZP), Medicines Act (medicines with psychoactive properties) or, in the case of caffeine, the Food Act (1975, 1981, 1996). Medicines are registered and require consent before they are released on the market (Medsafe, 2011). The registration process evaluate the safety, quality and efficacy of a medicine. This is done by reviewing both pre-clinical and clinical data, manufacture, formulation, and subsequent post-marketing surveillance and pharmacovigilence. Furthermore, a medicine has a therapeutic purpose, hence the efficacy of therapeutic purpose is paramount to registration of a medicine. New psychoactive substances in the context of the NPSR do not have a therapeutic effect (as traditionally defined by medicine). The new regulations will thus establish safety without establishing whether or not these substances have the effect they claim to have which may be relevant to the way they are perceived by consumers.

The NPSR proposes to determine ‘low harm’ through an “assessment of toxicological and behavioural data by an expert technical committee, taking into account likely harms to physical and mental health, the potential for dependence and withdrawal and societal implications, for example, whether using the product might cause aggression” (Office of the Associate Minister of Health and Cabinet Social Policy Committee, 2012a). The onus of evidence will be placed on the manufacturers of these substances, who will be required to demonstrate a level of ‘low harm’ (Treasury, 2011, p.10). To date, the details of the level of evidence the format required for such evidence is lacking. However, it is likely that
manufacturers will be required to engage the services of experts to evaluate and collect evidence. Potential partnerships for this research would be between the party pill and pharmaceutical industry, and with the academic community. However, undertaking research for the party pill industry will require careful consideration by Universities as entities, and academics as individuals. Tensions already exist between universities and commercial organisations, where commercially driven and funded academic research can lead to perceived or real conflicts of interest. Undertaking research for the party pill industry will require careful consideration by Universities as entities, and academics as individuals.

It is also unclear to what extent the new regulations will control claims of specific ‘effects’ by the manufacturers in comparison to those made by the marketers of food supplements, vitamins and herbal remedies. For example will statements about specific effects be allowable on the label or will it be reliant on the purchaser to establish whether the product induces the claimed effects? Looking to the future, it will be essential to collect post marketing data for evaluation to ensure that the products released are not causing long-term health issues. Finally will registration of psychoactive substances as ‘safe’ through evaluating the risk of harm be viewed by the public as an endorsement of efficacy and without risk of harm? In the case of BZP party pills, research indicated that when their availability was unregulated, younger consumers perceived that the product was approved by Government, and thus probably safe and ‘effective’, although likely to possess only weak effects (Sheridan and Butler, 2009). The fact is that no psychoactive substance will ever be entirely safe for all people.

Government has indicated that the manufacturers of new recreational drugs must consider acute and repeat dose toxicity, and human clinical trial data. However, a range of effects on both mood and broader physiological functions that could be categorised as either desirable or undesirable in a regulatory context could also be explored.

Undesirable effects include those beyond the effects of a single substance, for example the potential for drug interactions or synergy with other drugs currently prescribed. Furthermore, individual variations in the way in which new substances are potentially metabolised may result in harmful effects (Stingl et al., 2012). Other issues which would need to be considered are effects on seizure threshold and therefore the likelihood of inducing seizures (Haddad and Dursun, 2008), impaired cardiac or respiratory function (potentially fatal in overdose) (White and Irvine, 1999), and negative effects on cognitive function (Cromer et al., 2010).
Furthermore, consideration needs to be given to the new drug being a pro-drug which is metabolised to a more active, and potentially more toxic form (Kalapos, 2002).

On the other hand, desirable effects in a regulatory context might include the drug being suitable for oral ingestion only, meaning it will be considerably less likely to lead to the development of drug dependence in comparison with inhaled or injected drugs (Everitt and Robbins, 2005), and also reduce the risk of transmission of blood borne viruses through sharing injecting equipment (Hagan et al., 2005). Furthermore, the substance would have limited effect on cognitive function (Levin and Rezvani, 2002). An impact on cognitive function is also one of the reasons why people use ‘mind altering drugs’ and so herein lies the dilemma for regulators. Drugs which might be desirable to the consumer that significantly impair cognition following small and subsequent incremental doses are unlikely to show a low risk of harm and, therefore, be unlikely to meet regulatory requirements of an NPSR.

The Government makes it clear that even with a rigorous testing regime it is not possible to screen for all adverse reactions from new psychoactive substances as people have different sensitivities and consequently individuals who choose to use them must assume some risk. The question is to what extent is the regulator responsible for the health consequences of products once they have been approved.

Another important consideration in exploring the idea of regulated legal highs is examining the implications for public health. The legality or illegality of a mood-altering drug could have a number of both positive and negative consequences on the health and wellness of a population. One clear advantage of regulation over prohibition is that it enables more open engagement with how use unfolds. Regular users are more likely to talk openly about the issues they encounter and health agencies are in a better position to respond without those barriers associated with illegality such as secrecy, negative public reaction and social stigma (Luoma et al., 2007). This means that collection of post marketing data, and pharmacovigilence studies of adverse events will be simpler to implement. It also enables the open and officially endorsed development of harm reduction initiatives, such as public education, responsible marketing and positive using environments. All these become more difficult to resource and implement when access to the product is illegal.

This new regulatory framework also gives consumers a greater choice of legal psychoactive substances and, theoretically, access to substances which are at least no more harmful than alcohol. Within this environment, it may be possible to encourage young people to switch
from consuming large quantities of alcohol, with all its attendant consequences, to a safer alternative consumption pattern.

Experience with tobacco and alcohol has highlighted how commercialisation can pose significant challenges to public health. A key concern is the capacity of industrial complexes to deploy their profits in fostering pro-consumption influences with the public and with governments (Babor et al., 2010, Adams et al., 2010). This is typically achieved through activities such as lobbying, advertising, gifts and other inducements, and through management of researchers (Miller et al., 2011, Chapman and Shatenstein, 2001, Bond et al., 2010). With potential profits stake, and with protection of a growing market as a priority, a flourishing ‘legal high’ industry may choose to pursue a similar direction to that pursued by alcohol and tobacco producers.

Indeed, during the unregulated phase of legal highs in New Zealand, party pill producers invested considerable energy in many of the same pro-consumption activities seen with alcohol and tobacco, such as advertising and marketing, and were considered to be aimed at a youth market (Sheridan and Butler, 2007). Identifiable spokespeople emerged advocating on behalf of party pill producers regarding their minimal impacts and their potentially positive benefits, in the form of the Social Tonics Association of New Zealand (STANZ) – an industry body set up to self-regulate. Analysis of the retail restrictions proposed and voluntarily adopted by STANZ members to control the harms from BZP indicated they were not strong enough to bring about significant changes in BZP related harms (Wilkins and Sweetsur, 2010).

Although there will be strict control over retail availability and advertising, what is of concern is whether the regulatory framework underpinning access to legal highs is capable of withstanding the pressures that will inevitably emerge once a legal high industry develops the capacity to push its own interests. The regulatory framework is putting in place constraints on key aspects such as age and advertising. However, as producers accumulate profits and move towards collective action, they could move into a similar position to tobacco and alcohol producers where they exert pressure on policy makers to reduce these constraints (Adams et al., 2010). Conversely, experience with these existing industries may result in the development of a regulatory framework which is more resistant to such pressures, should they arise.
One further question concerns how current regulated industries, particularly liquor producers, might respond to other legalised psychoactive products in the market. For example, a beer producer might view these new products as a way of diversifying their business and they would have the means to exert influence on the political establishment. Their input could make it difficult to impose further regulations known to effectively reducing harm.

Whether or not established industries opt to contest or support legalised highs, all parties will be taking a keen interest in research, particularly research on the nature and extent of harms which will, in turn, inform the extent to which the industry is constrained. For this reason, a nascent legal high industry will be highly sensitive to research activity.

**Conclusion**

This paper has described the development of an innovative approach to controlling emerging psychoactive substances and considered some of the many consequences both positive and negative about the proposed framework. As this approach begins to flirt with the possibility of a regulated response consolidate to psychoactive drugs it leaves a number of uncertainties. It does, however, offer the opportunity of a more nuanced response to drug problems than the default prohibition response. In exploring this approach we need to remind ourselves of the mixed record of success in regards to the control of alcohol and tobacco use and related health and social harms.

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