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Policy Analysis

A critical analysis of the implementation of a legal regulated market for new psychoactive substances ("legal highs") in New Zealand

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ABSTRACT

Background: In July 2013 New Zealand passed the *Psychoactive Substances Act* (PSA) to establish the world's first regulated legal market for new psychoactive substances (NPS) ("legal highs").
Aim: To critically analyse the implementation of the PSA.
Methods: Synthesis of findings from interviews with 30 key informants (i.e. politicians, civil servants, legal high industry actors, toxicologists, NGO representatives and drug policy academics), analysis of relevant laws and policy documents, and a review of academic and grey literature on the PSA.
Findings: Key challenges experienced during the implementation of the PSA included the harmfulness of interim approved products, the slowness in withdrawing products which caused adverse effects, enforcing retail restrictions, price competition by retailers, judicial challenges by the "legal high" industry, and growing opposition to the regime from local communities and key stakeholders (including local councils). The PSA lacks a tax on products and restrictions on retail opening hours which likely contributed to the problems above. The implementation of the PSA also appeared to suffer from a rushed legislative process and resource constraints on the regulatory agency which led to delays in the development of the full regulatory framework, including the product testing requirements, and issues with enforcing retail regulation, such as the minimum age of purchase. The decline in public support for the PSA regime reflected problems with communicating the aims of the policy to the general public.
Conclusions: The troubled implementation of the PSA underlines a number of important lessons for consideration when developing a regulated legal drug market, including advanced development of regulatory systems, ensuring the sale of low risk products, adequately resourcing regulatory agencies and related enforcement activity, detailed regulation of retail outlets, establishing price controls, and ongoing engagement with stakeholders and the general public.

Introduction

The proliferation of new psychoactive substances (NPS), often marketed as so-called "legal highs", has challenged the international drug control system in recent years (Brandt, King, & Evans-Brown, 2014). Overwhelmingly, the policy response has been to attempt to prohibit sale of NPS using national drug laws (King, 2013). This approach has been criticised for reinforcing the "cat and mouse" game where manufacturers continually seek to introduce new uncontrolled compounds. More recently, a number of countries, including Ireland, Poland, Romania and the United Kingdom, have imposed so-called "blanket bans" on the sale of all products with psychoactive properties (notably excluding alcohol, tobacco, and medicines). This response has received intense criticism due to the practical challenges of enforcement (Malczewski, 2015), restrictions imposed on pharmacological research (Kavanagh & Power, 2014), for driving NPS users underground (Stevens, Fortson, Measham, & Sumnall, 2015) and issues with the interpretation of the legal definition of "psychoactivity" (Reuter & Pardo, 2017).

The problematic nature of prohibition-based responses to NPS was the driver for New Zealand's pre-market approval approach based on market regulation rather than prohibition (NZLC, 2011). The commercial market model was lobbied for by the existing "legal high" industry, who had accumulated significant financial resources from the BZP "party pills" market which operated in New Zealand in mid-2000s, and the idea was legitimised by the New Zealand Law Commission, an independent expert legal advisory body to the government, who in their 2011 review of the *Misuse of Drugs Act* recommended the establishment of a regulated market model to address the then unregulated "legal highs" sector (NZLC, 2011; Wilkins et al., 2013). In July 2013, the New

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Zealand Parliament passed the *Psychoactive Substances Act* (PSA), under which NPS developers are permitted to legally manufacture and sell psychoactive products subject to new market regulations (i.e. sale to minors under 18 years old prohibited, licensing of retailers and manufacture), provided they can prove evidence their products cause no more than a "low risk" of harm to consumers (Wilkins, 2014a). The New Zealand approach received considerable international attention as a "long-term" (UN, 2013), balanced (EMCDDA, 2015), and "bold and innovative" policy solution to the ongoing NPS problem (UK NPS Review Expert Panel, 2014) which, if successful, could potentially be adopted in other countries (Seddon, 2014). A number of authorities around the world expressed interest in monitoring progress with the implementation of the PSA (Commission on Narcotic Drugs, 2016; EMCDDA, 2015; UK NPS Review Expert Panel, 2014; UNODC, 2013).

At the time of the PSA's enactment, detailed regulations for the legal market were still being developed (including the product testing requirements), and consequently an "interim regime" was established. Under the interim regime, 153 retailers were licensed to sell 47 interim-approved products. A new government agency, the Psychoactive Substances Regulatory Authority (PSRA) was established to oversee implementation of the regime. However, after 10 months of operation, the "interim regime" was brought to an abrupt end following ongoing public protests and reports of adverse effects from products (MOH, 2014c). Despite this, the PSA remains in legal force and the envisioned full regulatory regime may yet be activated via a successful product approval or, as recently proposed, be utilised to regulate other drugs such as cannabis (New Zealand Herald, 2017a). Indeed, in the last five years a number jurisdictions in the United States, and Uruguay and Canada, embarked on policies to legalise cannabis and are now involved in their own implementation processes (Caulkins & Kilmer, 2016; Caulkins, Kilmer, & Kleiman, 2016; Room, 2014). The experience with the implementation of the PSA may well hold important lessons for these jurisidictions and others contemplating enacting legal regimes for psychoactive drugs.

The aim of this paper is therefore to present a comprehensive analysis of the implementation of PSA. It draws on in-depth interviews with 30 key informants (i.e. politicians, civil servants, legal high industry entrepreneurs, legal high industry workers, toxicologists and NGO representatives and drug policy academics), analysis of relevant laws and policy documents, and a review of academic and grey literature.

Challenges with implementing the PSA

Identifying interim approved products and monitoring their risks

Products approved for sale during the interim PSA regime included 40 synthetic cannabinoid (SC) smoking blends, one SC pill and a range of "party pills" with ingredients commonly used in dietary supplements (e.g. citrus aurantium, kava, caffeine, vitamin B) (Table 1). The interim approval criteria required products to have been on the market for at least three months prior to the PSA and not have attracted any significant reports of adverse effects. However, official data about adverse events from products was largely unavailable at the time the PSA was passed (Rychert, Wilkins, & Witten, 2017a). Forty-seven of the 63 product applications (i.e. 75%) received interim approval (Hannah, 2014) and this high proportion of approvals may reflect limitations in the data available. Some of the compounds used in the interim approved products were particularly potent synthetic cannabinoids when compared to THC in natural cannabis (Hermanns-Clausen, Kneisel, Szabo, & Auwärter, 2013; Wilkins, 2014b), and have subsequently been banned in other countries (e.g. AB-FUBINACA, PB-22, PB-22-5F, 5F-ADBICA) (e.g. China Food & Drug Administration, 2015; Drug Enforcement Administration Department of Justice, 2014; *German Federal Narcotics Act*, 2014). A number of New Zealand studies have retrospectively identified serious health harms related to interim approved products (Glue, Courts, Gray, & Patterson, 2016; Glue, Courts, MacDonald, Gale, & Mason, 2015; Macfarlane & Christie, 2015; Wilkins, Prasad, Wong, Graydon-Guy, & Rychert, 2016). Industry actors reflected that the dominance of high potency SC products in the interim market meant lower strength and potentially safer products were not commercially viable (Rychert et al., 2017a). "*People just wanted the strongest products*" – was the assessment of one key informant from the industry. Interviewed industry actors also noted the lack of regulatory flexibility during the interim regime favoured strong product formulations:

> *Once the new [interim] regime came into effect, these blends were "locked in" and could not be varied in any way. And since no new blends [products] could be introduced [until the full testing framework was finalised], there was no way to tone down or replace the products*. (industry)

The system for withdrawing harmful products during the interim market was criticised for its limited responsiveness. The framework to assess the risks of interim products was developed and released two months after the PSA was enacted (MOH, 2013). The system relied on anonymous telephone calls from the public to the free "Drug and Alcohol Helpline" and National Poisons Centre, reports sent by medical professionals to the Pharmacovigilance Centre, and reports made by a subset of hospital emergency units (MOH, 2013). The anonymous nature of calls made to the National Poisons Centre raised questions as to the quality and reliability of the data received. Industry key informants raised concerns about competitors making malicious calls to the poisons helpline in an effort to get their competitors' products withdrawn from the market. Other key informants focused on the limited information available from the Poisons Centre calls, for example:

> *The dosage wasn't mentioned. [For example, the Poisons Centre would ask:] "How much did you have?", [and the caller would answer:] "A couple of cones…" So you don't know what the dose is. You don't know what the circumstances of the event were. Polydrug use… Did they have the pre-existing history of psychiatric mental health issues? You don't know… you've got none of that*. (drug policy researcher)

Key informants reported many health professionals were not aware of the system for reporting adverse effects related to products through the Pharmacovigilance Centre (CARM) (Rychert et al., 2017a) and those directly involved in the process of monitoring products admitted the CARM data was "*not as useful as we thought they were going to be*" (civil servant). Finally, records from hospital emergency units were mostly unavailable for regulatory decisions because the system for coding hospital admissions in New Zealand [International System of Classification of Diseases (ICD)] did not include codes specific to SC. Key informants noted that codes were applied inconsistently across emergency departments and information about the specific brands involved in incidents was often missing (Rychert et al., 2017a). Another criticism was that some products containing a lower dose of a particular compound were withdrawn, while other products containing a higher concentration of the same ingredient remained on the interim market (Table 1). The explanation given for this apparent inconsistency was that there was considerable variation in manufacturers quality, which impacted the harmfulness of products:

> To be frank, the quality of manufacturing of these products was quite low, so it's entirely feasible (…) that this product made by this manufacturer is a problem, but [the same] substance [in a different product] made by another manufacturer may not be. (…) We decided that we would treat them separately, and we would go [assess] brand by brand. (civil servant)

Eleven products were withdrawn from the market during the interim regime: five in January 2014 (Wilkins, 2014b) and six in May 2014 (MOH, 2014a) (i.e. a mere week before the interim regime was ended) (Table 1).