

New Zealand's Groundbreaking Regulatory Model for New Synthetic Drugs



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After first attempting to prohibit various synthetic drugs, New Zealand realized that simply banning these substances was unrealistic and ineffective. In July 2013, the country's Parliament enacted an historic new law that will regulate and control – rather than criminalize – so-called “bath salts” and other new synthetic drugs.

New Zealand's Historic Model for Regulating Synthetic Drugs

After first prohibiting various synthetic drugs, such as the stimulant Benzylpiperazine (BZP), in 2008, New Zealand realized that simply prohibiting these substances was an “untenable” approach.¹ So, in July 2013, the country's Parliament enacted a landmark law that will regulate and control – rather than criminalize – so-called “bath salts” and other new synthetic drugs. The first-of-its-kind law, the Psychoactive Substance Act of 2013, came into effect on July 18, after being approved in Parliament by a 119-1 margin, with the support of seven different political parties from across the political spectrum.²

The law creates a new government agency within the Ministry of Health, the Psychoactive Substances Regulatory Authority, which is charged with ensuring that synthetic psychoactive products meet adequate safety standards before going to market. The new regulatory body will also implement and administer a licensing system for potential manufacturers, importers, wholesalers, retailers and researchers.

The law immediately established several restrictions:

- a minimum purchasing age of 18;
- restrictions on retail outlets, including a ban on sales in convenience stores;
- requirements for labeling and packaging, including mandatory health warnings and ingredient list; and

- a ban on advertising except at the point-of-sale.

As an island nation that produces (rather than imports) most of the illegal drugs it consumes, New Zealand has struggled with the emergence of unregulated synthetic drugs.³ Unlike other countries that have criminalized these substances, however, New Zealand will now allow businesses to sell such products – *but only if they can prove their product meets basic consumer safety standards.*⁴

Individuals and companies who wish to apply for approval of a new drug product must first demonstrate that it poses “no more than a low risk of harm” to consumers.⁵ The application process requires the product to undergo rigorous clinical trials to examine toxicity and addictiveness (at the producer's expense). The trial results will then be evaluated by an independent expert advisory committee.⁶ If an approved drug is found to be more harmful than shown in trials, it can simply be removed from the market. The law also contains a built-in review after five years to ensure that it is functioning as intended.⁷

“Regulating psychoactive substances will help protect the health of, and minimize harm to, individuals who use these substances.”⁸

– New Zealand Ministry of Health, 2013

Potential manufacturers will be required to pay an estimated \$180,000 in application fees, plus \$1 million to \$2 million in testing costs for each product they wish to market. They face penalties of up to eight years in prison for selling banned substances, and two years for selling unapproved substances.⁹

Supporters of the legislation have argued that outright criminalization drives these products to the underground market, which provides no age

restrictions or other regulatory controls.¹⁰ What is more, attempts to ban one new substance after another have proven futile – each time one gets banned, another new, untested and oftentimes more dangerous drug fills the void to replace it.¹¹

“This regime will be fundamentally based on reversing the onus of proof so those who profit from these products will have to prove they are as safe as is possible... We will no longer play the cat-and-mouse game of constantly chasing down substances after they are on the market.”

– Hon. Peter Dunne, Associate Minister of Health, New Zealand.¹²

Another stated goal of the law is to prevent the criminalization of consumers and resultant harms. According to the Associate Minister of Health, “What we are trying to do is actually protect young people, not criminalize them and thereby jeopardize their job and travel prospects.”¹³

Permanent regulations will be issued in late 2014 and are expected to take effect in mid-2015. In the meanwhile, an interim regime has been established that has already proved successful in limiting the number of synthetic products on the market. The Ministry of Health reports, “The number of retail outlets selling psychoactive products has reduced from an estimated 3,000-4,000 unregulated sellers to less than 170 licensed premises nationwide, a reduction of around 95 percent,” since the law’s passage, while the number of products decreased more than 75 percent, from roughly 200 products to fewer than 50. Remaining products on the market – and all licensed sellers – are “now subject to active and on-going scrutiny” by health and law enforcement officials.¹⁴

“Simply banning these drugs only incentivizes producers to develop drugs that get around the law – regardless of what they will do to the people that take them. This model incentivizes producers to develop drugs that are safer. We think that’s a much smarter way to go about it.”

– Ross Bell, New Zealand Drug Foundation, 2013.

The Organization of American States (OAS) characterized the new model as “a regulatory framework for production and sale ... [that] puts the onus for reviewing and establishing product risks onto the producers, in the same way pharmaceutical companies must apply for a license to market a drug only after extensive testing.”¹⁵

New Zealand’s groundbreaking model for regulating synthetic drugs is an innovative, health-centered alternative to failed prohibitionist policies.¹⁶

¹ Peter Dunne, “Legal highs regime costs and penalties announced,” *Scoop NZ*, October 10 2012.

² Psychoactive Substance Act of 2013, <http://www.legislation.govt.nz/act/public/2013/0053/latest/DLM5042921.html>.

³ J. Sheridan and R. Butler, “‘They’re legal so they’re safe, right?’ What did the legal status of BZP-party pills mean to young people in New Zealand?,” *Int J Drug Policy* 21, no. 1 (2010).

⁴ Chris Wilkins et al., “The new psychoactive substances regime in New Zealand: a different approach to regulation,” *Journal of Psychopharmacology* 27, no. 7 (2013); Catherine McCullough, Jackson Wood, and Rob Zorn, “New Zealand’s psychoactive substances legislation,” (IDPC-New Zealand Drug Foundation Briefing Paper, 2013).

⁵ New Zealand Ministry of Health, “How the Authority is Assessing Interim Products,” <http://www.health.govt.nz/our-work/regulation-health-and-disability-system/psychoactive-substances/how-authority-assessing-interim-products>.

⁶ Ibid.

⁷ Catherine McCullough, Jackson Wood, and Rob Zorn, “New Zealand’s psychoactive substances legislation.”

⁸ New Zealand Ministry of Health, <http://www.legalhighs.co.nz/synthetic-cannabis/ministry-of-health-nz-psychoactive-substances-regulatory-authority-update/2013>.

⁹ Peter Dunne, “Legal highs regime costs and penalties announced.”

¹⁰ Catherine McCullough, Jackson Wood, and Rob Zorn, “New Zealand’s psychoactive substances legislation.”

¹¹ Ross Bell, “Why ‘party pills’ are legal in New Zealand: Our new law forces drug producers into the light of day and makes them responsible for safety.,” *USA Today*, September 25 2013; Chris Wilkins et al., “The new psychoactive substances regime in New Zealand: a different approach to regulation.”

¹² Ibid.

¹³ Peter Dunne, “Legal highs regime costs and penalties announced.”

¹⁴ New Zealand Ministry of Health, “Quick Facts about the Psychoactive Substances Act,” <http://www.health.govt.nz/our-work/regulation-health-and-disability-system/psychoactive-substances/quick-facts-about-psychoactive-substances-act>.

¹⁵ Organization of American States, “Scenarios for the Drug Problem in the Americas: 2013-2025,” (2013), 51.

¹⁶ Chris Wilkins et al., “The new psychoactive substances regime in New Zealand: a different approach to regulation.”