

PolicyTalk

New Psychoactive Drugs: No Easy Answer

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Introduction

This edition of Policy Talk reviews current knowledge of new psychoactive substances, a category of substances that is challenging government controls across the world, and compares how health authorities are responding to the challenges, with special reference to Australia and New Zealand.

Background

'New psychoactive substances' refers to substances that are produced to mimic the effect of an illicit drug such as cannabis, ecstasy, LSD, cocaine or amphetamines. They are known by various names including legal highs, herbal highs, research chemicals, analogues and synthetics. 'New psychoactive substances' (NPS) is the preferred term adopted by the United Nations Office for Drug Control for substances that may pose a risk to public health but are not scheduled by the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances, (UNODC, 2013).

Types

NPS fall under five broad categories:

- Cannabinoids (see below)
- Psychedelics including tryptamines, Ergolines (similar to LSD;) psychedelic amphetamines including the NBOME series
- Stimulants include substances related to cathinone, piperazine and amphetamine. This group includes mephedrone and MDPV (methylenedioxypropylvalerone), which are often sold disguised as 'bath salts' or 'plant food' and substitute for amphetamines or ecstasy.
- Dissociatives include substances related to ketamine and PCP
- Sedatives include opioid substances such as morphine, fentanyl and heroin

Other substances including indanes, benzodifuranyls, narcotic analgesics (such as codeine for conversion into desomorphine , synthetic cocaine derivatives, Salvia divinorum, ketamine) and phencyclidine derivatives (UN 2013). Many NPS are thought to be manufactured in India or China and exported to countries around the world.

Synthetic cannabinoids are currently the most common NPS in Australia and New Zealand. They are a group of chemicals that activate the same receptors in the brain as tetrahydrocannabinol (THC), the active ingredient in cannabis. Substances with a chemical structure similar to THC were first developed in the 1960s and a number of synthetic cannabinoids now known as the JWH compounds were synthesised in 1994; some are used in scientific studies which investigate the impact of THC on the animal and human brain (Dargan et al., 2011) To produce a synthetic cannabis product for use as a recreational drug

one or more synthetic cannabinoids is sprayed onto inert plant matter; various compounds of synthetic cannabinoids have been detected in herbal smoking products under brand names such as Spice and Kronic since 2006 (Dargan et al., 2011). Synthetic cannabinoids came to public notice in Australia in 2011 when miners in West Australia substituted Kronic for cannabis in order to avoid detection during workplace drug testing (Bright, 2013a).

In recent years new classes of drugs have become prominent, including the NBOMe or 25I-NBOMe family of hallucinogens that are sold as a substitute for LSD and have been used by humans only since 2010 (Barrat, 2013). As with synthetic cannabinoids, some of the new substances originated as manufactured chemicals for use in health, biological or medical research.

NPS often fall outside the international United Nations drug control conventions that cover other drugs such as heroin, cannabis and cocaine, although they are increasingly controlled in many countries under domestic law. Previously NPS were unregulated and quasi-legal, available for sale in sex shops and tobacconists, in head-shops which sell drug paraphernalia, and online. Due to their availability they have been perceived as legal, low strength and safer alternatives to illicit drugs (Sheridan & Butler, 2010). In reality, their use is hazardous because so little is known about them and in the case of synthetic cannabinoids, their active compounds are often many times more powerful than the THC found in natural cannabis (Wilkins, 2014a).

NPS challenge government control on illicit drugs because they are being manufactured across the world and marketed online via the internet, as well as disseminated by traditional black market avenues. The number of NPS reported to the UNODC rose by 50% between 2009 and 2012 when 251 separate substances had been identified (World Drug Report, 2013). In Australia, some products, especially synthetic cannabinoids, have been sold in shops and businesses under the guise of herbal products and marketed as 'social tonics'.

As NPS are new and unfamiliar, and their chemical structure is often modified to qualify as a novel, not-prohibited substance, the physical and psychological effects of NPS are unknown and unpredictable. Some substances are rushed to the market so quickly their manufacturers do not know the likely specific effects and they depend on consumers to report them (Winstock, 2013). Analysis of cannabinoid products has shown the concentration of active ingredient varies considerably over time in the same branded product (Zuba and Byrska, 2013).

Popular reasons for using NPS are similar to traditional motivations for use of drugs: curiosity, novelty, relaxation, altered consciousness and sensory experience, and to avoid giving a positive sample in a drug test. Reported negative effects include memory loss, confusion, anxiety, depression, hallucinations, paranoia and psychoses. Some synthetic cannabis products have been found to precipitate psychotic symptoms among people with pre-existing risk factors (Every-Palmer, 2010). Other risks are dependency, cardiac

complications, seizures and brain injury (Bright, 2013). Deaths have been reported in Australia and overseas either due to overdose of an NPS or to misadventure while under the influence of an NPS (ABC, 2013).

Prevalence

No reputable estimate of the prevalence of NPS has been published in Australia. In several European states (UK, France, Poland) it is estimated that around 5% of people 15-24 years have tried NSP (Bleeker, 2013). An Australian representative of licit retailers who sold NPS estimated the value of the 'legal market' at \$600 million in 2012 (Patton, 2013). This is without accounting for untraceable online sales through "deep internet" sites such as Silk Road.

In the mid-2000s, New Zealand had a particularly well-developed market for legal benzylpiperazine (BZP) 'party pills' (Sheridan et al. 2007). In 2006, 15% of the New Zealand population aged 13-45 years had used a BZP party pill in the previous year, including 40% of males aged 18-24 years (Wilkins et al. 2007). An estimated 200,000 BZP 'party pills' were sold each month in New Zealand in 2004, generating retail sales of \$24 million per year (\$NZ) (Wilkins & Sweetsur, 2010).

European action

In Europe, according to the European Monitoring Centre for Drugs and Drug Addiction, various means have been tried to reduce the availability of NPS (EMCDDA, 2013). Consumer protection laws that demand accurate labelling of products have been used in eight countries including Poland, Italy and the UK, and in Austria NPS have been brought under legislation that governs medicines. Some countries, including Finland and Hungary, have placed NPS under the control of existing drug laws, sometimes enacting temporary bans until they can be investigated fully. Initially, individual NPS were the subject of regulatory action, though it is common now for whole groups of drugs, or their analogues and derivatives, to be controlled. Several nations, including Ireland, Portugal, Austria and Romania, have passed new laws to control the unauthorised distribution of psychoactive substances, although the details differ in each case. Nevertheless, two long trends are noticeable: criminal sanctions are not being imposed upon individuals who use NPS while suppliers are likely to face imprisonment (EMCDDA, 2013).

Australian action

Australia has followed many countries and banned the importation and use of a range of individual substances and groups of substances under a combination of federal and state government laws. They include the Poisons Standard, the Criminal Code, Customs Regulations and consumer protection and fair trading laws. State governments have banned specific chemicals and specific derivatives, and the advertising and sale of NPS.

In 2011 the Therapeutic Goods Administration banned 8 synthetic cannabinoids under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) or 'Poisons Standard': this measure also applied to other substances due to the Standard's analogue and derivatives clause. Although the substances were therefore illegal in states and territories that automatically adopt the Poisons Standard into their own legislation, complementary legislation was required at state and territory level to enable police and other authorities in those jurisdictions to enforce the law. Most jurisdictions banned between 8 and 21 individual synthetic substances in 2011. In June 2013 under the Competition and Consumer Act the Commonwealth government imposed an interim ban on the sale of 19 synthetic cannabinoid products to provide time for state and territory governments to legislate their own prohibitions.

As manufacturers have evaded the regulations by altering the molecular structure of substances to produce new substances that do not fall within the prohibited categories, states and territories have continued to legislate for various measures. Among the latest, in 2013 South Australia passed an Act to enable police to close businesses that sell synthetic drugs and Victoria prohibited the cannabinoid Marley, and three of its constituent properties, which had come to notice for causing seizures and loss of consciousness (SGV, 2013). At that stage Victoria had banned a total of 10 unique substances and 9 classes of substances, and South Australia proclaimed "First we banned the chemical. Then we banned the product. Now we are introducing laws that prevent new products getting on to the shelves in the first place" (GSA, 2013).

More recently, several states have prohibited all psychoactive drugs, with the exception of existing legal drugs, under their misuse of drugs and drug trafficking Acts, in an attempt to pre-empt the continual production of new substances and the federal government signalled its intention to ban the importation of all unauthorised psychoactive substances. The placement of production and distribution of NPS under drug trafficking laws means offenders face more onerous penalties.

New Zealand action

New Zealand has a long history of legal high use with large markets for BZP 'party pills' and nitrous oxide in the mid-2000s, followed by 1-3 Dimethylamylamine (DMAA) 'party pills' and salvia divinorum in the late 2000s, and most recently synthetic cannabis (e.g. Kronic, K2) (Wilkins et al., 2013a). A number of policy responses have been tried to address the problem including analogue provisions within the Misuse of Drugs Act (MODA), a 'restricted substances' category within MODA (i.e. known as 'Class D') and Temporary Class Drug Notices (i.e. allowing immediate 12 months bans to be imposed on compounds) (Wilkins et al., 2013b). In 2009, the New Zealand Law Commission was asked to conduct a first principle review of MODA, including the approach taken to new psychoactive substances (NPS) (i.e. legal highs). They recommended the establishment of a pre-market approval regulated legal market for 'low risk' NPS (NZ Law Commission, 2011). This approach would 'reverse the onus of proof' from the government attempting to determine if a compound

was harmful after it had been introduced to the market, to manufacturers been required to show that an NPS product was 'low risk' before it was permitted to be legally sold (NZ Law Commission, 2011). The government adopted the Law Commission's recommendations and developed the new NPS regulatory regime over 2011 and 2012 (Wilkins et al., 2013b).

The enactment of the Psychoactive Substances Act 2013 (PSA) on the 18th July, 2013 established the new NPS regulatory regime in New Zealand (Wilkins, 2014a). Under this new approach, manufacturers are able to apply for government approval to legally manufacture and sell an NPS product if they can demonstrate with 'toxicology and clinical trial data' that the product poses a 'low risk' of harm to users (Wilkins, 2014b). Approved NPS products will then be sold subject to a range of retail restrictions and other regulation including supply of NPS products restricted to those 18 years or older, and sales prohibited from convenience stores (e.g. corner stores, supermarkets), places that sell alcohol, and outlets which sell automobile fuels (Psychoactive Substances Act 2013). Licensed products are required to be labelled with health warnings, a list of active ingredients, the contact details of the manufacturer, and the telephone number of the National Poisons Centre (NPC) help-line (Psychoactive Substances Act 2013). The advertising of licensed products is restricted to the 'point of sale' only (i.e. no advertising in t.v., radio or newspaper) (Psychoactive Substances Act 2013).

Proponents of this approach argue it places the onus on manufacturers to show NPS products are safe in advance of sale, removes high risk NPS products from legal sale, requires the industry rather than the government to bear the financial costs of testing products, and subjects NPS products to a range of retail restrictions (Dunne, 2012). However, key questions remain concerning how the standard of 'low risk' will be defined in practice, what scientific tests will be required to demonstrate a product is 'low risk', and the extent to which a legal market for approved NPS products will encourage the use of NPS and other drugs (Wilkins, 2014b). A pivotal issue from a health perspective is the extent to which people may substitute existing more harmful drugs for approved 'low risk' legal highs, and the overall impact for drug-related harm (Wilkins, 2014b).

The New Zealand approach has attracted considerable international attention as a possible future model for the control of NPS in other countries, and even for existing illegal drugs, such as cannabis (Meacher, 2013). The enactment of the PSA brought about a number of immediate changes to the 'legal high' sector in New Zealand (Wilkins, 2014a). All NPS products, and the people and companies involved in their manufacture, distribution and retail sale, are now required to be licensed. All unlicensed NPS products are prohibited by default (Wilkins, 2014a). As a result of the licensing requirements, the number of NPS retail outlets fell from an estimated 3,000-4,000 largely convenience stores to 156 specialty stores, and the number of legally available NPS products fell from 200 to less than 46 (Wilkins, 2014a).

A product safety assessment framework has been developed to determine if a product should receive an interim license (Wilkins, 2014a). The effectiveness of this framework will

depend on the quality of the data available on adverse cases (Wilkins, 2014a). This is a challenge as self-reported information from users is often unreliable, and in some cases emergency department staff do not have all the information required to make an accurate assessment of a product (Wilkins, 2014a).

Next steps

The PSA merely created the legislative framework for the new NPS regime. A range of secondary regulation is still needed to be developed to make the new regime fully operational, including what scientific tests would be required to establish an NPS product as 'low risk' (Wilkins, 2014a). Consequently, as of late February 2014, no NPS product is yet to be assessed under the full regime, and the indication is the required secondary regulation will not be available until June 2014

Among the administrative and regulatory issues that may be addressed are:

The testing regime: How low-risk is defined and the criteria used to determine low risk; whether manufacturers of NPS and the government are indemnified against claims of adverse consequences borne by consumers.

Packaging/labelling of product: whether controls are placed on names of commercial products; whether health warnings will be mandated on packaging, and, if so, their nature; the means by which they will be conveyed; whether plain packaging will be adopted.

Public safety: How workplace safety and road safety will be accommodated in light of the legal availability of additional psychoactive substances.

Price: How price points for NPS will be determined; whether the price will reflect the various and full costs of regulation including licensing, quality assurance, public education, and health, hospital & law enforcement systems.

Taxation: How much excise (tax) will be levied on the product and how will it be applied e.g. by weight, by dose, or other measure;

Current situation in Australia

In Australia the production, importation, distribution, sale, and consumption of NPS remains illegal. Despite their illegal status, and uncertainty over their chemical constituents, composition, and psychoactive effects, NPS are purchased via the internet and from shops and businesses that sell them 'under the counter'.

Persons who use NPS, and those who may be attracted to them, need to understand the risks as NPS are often more powerful than the drug types they are purported to mimic and little is known of their effects. Otherwise, as with many other types of substance use, risks

increase when a whole dose is taken at once or when multiple doses are taken over a short period; when it is combined with another substance; when it is used alone, or in company with a person who is affected by alcohol or drugs; or when it is taken by a person who is unbalanced or unwell, or by someone with a personal or family history of mental illness.

Australia's Inter-Governmental Committee on Drugs (IGCD) has a role in monitoring the development of the New Zealand pre-market NPS regulatory scheme which is due to commence in mid-2014. The immediate and longer term impact of legalising 'low risk' NPS on alcohol and other drug use and levels of drug related harm is unknown. Although New Zealand's drug culture is not identical to Australia's, the NZ experience of legal NPS will be relevant to the future Australian response.

Use of NPS should be included in drug monitoring surveys in Australia. Inclusion of NPS in public drug surveys will enable health authorities to monitor the use (prevalence and incidence) of NPS within the broad population and within specific demographic groups. This will allow appropriate preventative information to be targeted to those who are in most of it and support the development of policies that are most likely to be effective in reducing drug related harm.

Interested members of the public need access to accurate and relevant drug information, and this is especially important for NPS where there is still so much unknown about their potential harms. NPS should be addressed within the school drug education curriculum, so that both students and parents become aware of the issues. Parents can also get further information and advice from the ADF's The Other Talk website which supports parents to communicate constructively with their children about drugs and alcohol, including NPS. More information on NPS is available from the ADF's DrugInfo website which is regularly updated as new information and data becomes available.

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