

INQUIRY INTO LAW REFORM ISSUES REGARDING SYNTHETIC DRUGS

Organisation: NSW Government
Name: The Hon Barry O'Farrell MP
Position: Premier
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NSW GOVERNMENT SUBMISSION
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A broad range of synthetic drugs have emerged in recent years that have similar effects to prohibited drugs, and synthetic cannabinoids are the most recent group of substances to have done so. Synthetic cannabinoids are the most pressing category of synthetic drugs for jurisdictions currently, and are the focus of this submission.

It is anticipated that the trend for synthetic drugs will continue into the future, aided by ongoing developments in communication technologies. Emerging synthetic drugs present challenges for legislators, police, researchers and health professionals.

SYNTHETIC CANNABINOIDS

Cannabinoids are a structurally diverse family of compounds with a large number of biological targets and can be classified into three groups:

- phytocannabinoids;
- endocannabinoids; and
- synthetic cannabinoids.

Synthetic cannabinoids are a large family of chemically unrelated structures which act like delta-9-tetrahydrocannabinol (THC), the active ingredient of cannabis. Synthetic cannabinoids are functionally similar to THC and, as with THC, they bind to the same cannabinoid receptors in the brain.

Since the 1960s, many analogues (ie substances with similar chemical structures) of THC have been developed, including HU-210, which is reported to have 100 times the potency of THC. In 1994, JW Huffman and colleagues synthesised a large series of synthetic exogenous cannabinoid receptor agonists, including a number of what are now known as JWH compounds, after the name of their inventor. These included JWH-015, JWH-018, JWH-073, and JWH-398.

Since approximately 2004, herbal mixtures marketed as incense or air freshener became widely available across the world via the Internet or head shops¹ and began to be used as a substitute for cannabis. Warnings on the products stated that they were not intended for human consumption, but these messages were a dramatic contrast to the accompanying marketing which promoted the products as a cannabis alternative which was undetectable by conventional drug testing.

¹ A head shop is a retail outlet specialising in drug paraphernalia used for consumption of cannabis, other recreational drugs, legal highs, legal party powders and New Age herbs, as well as counterculture art, magazines, music, clothing, and home decor.

The wide range of these products typically contained between 1-3g of dried plant matter and their labelling declared the contents to be a variety of 'herbal blends' which were completely legal. Based on these accounts the products were not banned by European authorities. Instead their popularity as 'legal drugs' dramatically increased based on their reputation of being "potent herbal intoxicants" and legal alternatives to cannabis.

In Europe, amongst the first and certainly the most well-known of these herbal mixtures was a brand known as 'Spice', with a range of products being available, eg Spice Silver and Spice Diamond. Since the Spice brand first appeared in 2004, a large number of competing products made by other manufacturers also became available.

In December 2008, the German company THC Pharma reported JWH-018 as an active ingredient in Spice products and as a result, German health authorities prohibited the synthetic cannabinoids identified in the product (JWH-018 and CP 47,497-C8). The herbal ingredients cited on Spice's packaging did not appear to contribute to its psychoactivity, and in fact they were not even present in most of the samples tested.

Further studies have discovered that there is also variability in the combinations and concentrations of the synthetic cannabinoids within Spice products such that using different brands, or even different batches of the same brand, can produce dramatically different effects.

NSW Health advises that it is now believed that the synthetic cannabinoids receptor agonists are sprayed in a liquid solution onto a mixture of "smokable herbs", which, once dried, is packaged and made available for sale to users.

Who uses synthetic cannabinoid products and why?

There are limited epidemiological data regarding the use of synthetic cannabinoids and little is known about the effects users of these products experience, apart from those mentioned in case reports where they have presented to emergency departments.

In Australia, the Ecstasy and Related Drugs Reporting System provides a national monitoring system that annually interviews regular ecstasy users. One of its aims is to identify emerging trends, and in 2011 questions were asked about the use of synthetic cannabinoid products. Overall, numbers amongst the national sample were small with only four people reporting using K2/Spice, with 32 (6% of the national sample) reporting the use of some other cannabinoid in the previous 12 months. The Western Australia sample was the most likely to report use of these products.

In addition, media outlets in Western Australia reported that "mineworkers" were "getting high" on a synthetic cannabis that impairs their ability to operate machinery, but cannot be detected by drug and alcohol tests used at the sites. The reports also stated that the product was "five to 10 times stronger" than THC and had been banned in 16 countries after being linked to deaths. Mineworkers were interviewed

and claimed that they had used the product and were randomly drug tested afterwards and had escaped detection.

The Commonwealth Therapeutic Goods Administration, acting on a referral from the Western Australian Government, has since mid 2011 been considering whether, and how, wider restrictions on synthetic cannabinoids can be implemented.

Harms associated with use of synthetic cannabinoids

The effects of synthetic cannabinoid smoking blends have been reported to be similar to those of cannabis, such as relaxation and sedation. Commonly reported effects include paranoia, anxiety, racing thoughts and irritability. Other effects also include hallucinations, tremors, seizures, drowsiness, slurred speech, dilated pupils, elevated blood pressure, vomiting and chest pain. There have also been reports of psychosis in patients with a history of mental illness.²

The NSW Ministry of Health's Mental Health and Drug & Alcohol Office has developed a fact sheet on synthetic cannabinoids, warning of the dangers of using these substances. A copy is available on the NSW Health website:
http://www.health.nsw.gov.au/factsheets/drugandalcohol/synthetic_cannabis.html

Long term effects of synthetic cannabinoids have not been established, such as the cumulative toxic effects these compounds or their metabolites may have.

Synthetic cannabinoids are often classified as 'research chemicals'. Research chemicals are experimental chemicals that are not approved for human consumption. The vast majority of these chemicals have only been recently synthesised and up until very recently, little, if any, data have been available regarding their effects, adverse reactions, toxicity, drug interactions, long-term damage, or dependence potential with regard to humans.

Almost all of the available published data on the harms relating to the use of synthetic cannabinoids by humans deal exclusively with the range of 'Spice' products and one particular compound – JWH-018.

NSW Health advises that the first case report related to a Spice product was published in 2009 after two of the authors smoked 0.3g of 'Spice Diamond'. The effects reported included reddened conjunctivae, increased pulse rates, xerostomia (dry mouth), and an alteration of mood and perception.

Since that time there have been reports from across the world, in countries where these products have been available, of emergency presentations for a range of adverse effects, including tachycardia, agitation, excess sedation and a loss of consciousness as a result of their use.

²Therapeutic Goods Administration, <http://www.tga.gov.au/industry/scheduling-decisions-1202-final.htm> 'Final Decisions & Reasons for Decisions by Delegates of the Secretary to the Department of Health and Ageing February 2012' p. 130

REGULATION OF SYNTHETIC CANNABINOIDS

Regulation of synthetic cannabinoids in NSW

Schedule 1 of the NSW *Drug Misuse and Trafficking Act 1985* (DMTA) contains a list of drugs and plants which are prohibited in NSW. The DMTA makes it illegal to possess or supply these substances.

In addition to the list of substances, Schedule 1 also prohibits any analogues of substances listed in the Schedule. An analogue is defined as a substance that has psychotropic properties, which is obtained by structurally modifying a prescribed substance in a number of specified ways.

Section 44 of the DMTA allows Schedule 1 to be amended by adding or amending names or descriptions relating to prohibited plants and substances. The analogue provisions and the ability to rapidly amend Schedule 1 are the two ways in which NSW legislation is able to respond to variations in illicit drugs.

Due to recent concerns regarding synthetic cannabis products, Australian jurisdictions have taken steps to prohibit such substances. NSW inserted seven synthetic cannabinoids into Schedule 1 in July 2011 by way of regulation:

- JWH-073 (1-Butyl-3-(1-naphthoyl)indole)
- CP 47, 497 (5-(1,1-Dimethylheptyl)-2-[(1R, 3S)-3-hydroxycyclohexyl]-phenol)
- Cannabicyclohexanol or CP 47,497 C8 Homologue (5-(1,1-Dimethyloctyl)-2-[(1R, 3S)-3-hydroxycyclohexyl]-phenol)
- JWH-250 (2-(2-Methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone)
- JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)
- JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)
- JWH-018 (1-Pentyl-3-(1-naphthoyl)indole).

Following the ban on these seven synthetic cannabinoids, manufacturers quickly re-synthesised their products, replacing banned compounds with other synthetic cannabinoids not covered by the ban.

Manufacturers of these products gave re-synthesised products new names that were similar to older products (for example, 'Northern Lights Golden Breeze' replaces 'Northern Lights', and 'Kronic' has been replaced by 'Kronic 2' or 'Black Label Kronic'). This suggests there may be an attempt to maintain some kind of 'brand loyalty'. The NSW Government is currently seeking legal advice on the appropriate approach, to ensure that all of these re-synthesised products are banned under NSW legislation.

The NSW Police portfolio believes that there are hundreds of synthetic cannabinoid compounds that could potentially produce similar effects to cannabis and other synthetic cannabinoids.

When new variants of synthetic cannabinoids are developed and marketed, in the short to medium term they will be illegal if a) they fall under the analogue provision or b) a regulation is passed adding the substance to Schedule 1. If the substance falls

under a) it will be illegal from the time it was created. If it falls under b) it will be illegal from the date of the regulation.

Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons

The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) promotes uniform scheduling of substances and uniform labelling and packaging requirements throughout Australia.

Schedule 8 of the SUSMP prescribes controlled drugs, that is, substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

Schedule 9 of the SUSMP prescribes prohibited substances, that is, substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.

Schedules 1 through 8 of the SUSMP are automatically adopted by reference into the poisons list under the NSW *Poisons and Therapeutic Goods Act 1966*. Among other things, this Act regulates the sale of substances which have therapeutic uses, but to which certain conditions should apply (eg only to be supplied by healthcare professionals) due to their toxicity or potential for misuse. Offences under this Act generally attract comparatively minor penalties. This can be contrasted with the DMTA, which deals primarily with illicit drugs of addiction, and under which very serious penalties are available.

Schedule 9 of the SUSMP is not currently adopted under the NSW *Poisons and Therapeutic Goods Act*. It could not be automatically adopted into Schedule 1 of the DMTA as the applicable provisions and penalties for offences such as drug trafficking differ depending on the quantity of the substance involved. Schedule 9 of the SUSMP does not prescribe quantities.

Regulation of synthetic cannabinoids in other jurisdictions

On 17 June 2011, Western Australia implemented a ban via state-specific legislation of seven synthetic cannabinoids. Within several days of the release of the intent to ban these substances, an alternative synthetic cannabinoid formulation was being marketed claiming to circumvent these controls.

On 5 August 2011, the Western Australia Government banned 14 more synthetic cannabinoids hours after a 38 year old Perth man died after "suffering a heart attack" reportedly after smoking Kronic Black Label, a product that distributors had claimed was not covered under the previous legislation.

Commonwealth scheduling decisions may be implemented within States and Territories under local drugs and poisons legislation. Substances listed in Schedules 1 to 9 of the SUSMP are automatically adopted through reference in Victoria, the

Northern Territory and the Australian Capital Territory, and by other processes in Western Australia, South Australia, Queensland and Tasmania.

As noted above, NSW does not adopt entries in Schedule 9 of the SUSMP into Schedule 1 of the DMTA.

Policing synthetic cannabinoids

It appears that, for the most part, retailers of banned products have restocked with products that are marketed as legal, having none of the banned substances included in their composition. It is likely this is the case in most instances, however, police have nevertheless still detected some of the banned substances since early July 2011.

NSW Police Force data shows that from July 2011 to December 2011 there were 168 detections of synthetic cannabinoids.

It is not an offence to possess other variations of synthetic cannabinoids not specifically listed in Schedule 1 of the DMTA. However, issues surrounding inaccurate labelling, lack of ingredients on the label and inconsistency of ingredients in the products make it difficult for police to accurately determine whether or not substances they encounter include banned forms of synthetic cannabinoids.

Analysis of individual samples is necessary to conclusively determine whether a product contains any banned substances.

Current analogue provisions of the DMTA have resulted in successful prosecutions in respect of other synthetic drugs such as mephedrone (which is structurally similar to the prohibited substances methcathinone and cathinone).

Synthetic cannabinoids differ in chemical composition to cannabis/ THC. There is also significant variation between different types of synthetic cannabinoids.

Issues to be considered when regulating synthetic cannabinoids

The issue for consideration when prohibiting synthetic or designer drugs was described by the Model Criminal Code Officers Committee (MCCOC) in their 1998 Report on Serious Drug Offences:

"The definition of [synthetic] drugs must be sufficiently flexible to include newly developed designer drugs, but sufficiently determinate in meaning to enable agreement between expert witnesses. The definition should not lend itself to dispute over issues of interpretation. Existing legislative references to 'derivatives' and drugs of 'similar pharmacological effect' lack determinate meaning and lend themselves to dispute between expert witnesses because they involve comparisons which are essentially matters of impression. Certainty rather than interpretative license is essential [when severe penalties are available]"

Ultimately MCCOC adopted a definition in the Model Criminal Code which largely mirrors the analogue provision in Schedule 1 of the DMTA, but which excludes the requirement for the substance to have a psychotropic effect.

A fact based approach

As noted above, in order for a non-prescribed substance to be prohibited under the NSW analogue provision, the substance must have psychotropic properties. This phrase is not used elsewhere in Australia.

Analogue provisions in each Australian jurisdiction differ sufficiently from each other to make categorisation difficult, but the Australian Capital Territory and Northern Territory have substantially similar provisions to NSW, with the addition of substances which are “otherwise structurally similar” to prohibited substances. Victoria and Queensland prohibit any salts, derivatives, or isomers of prohibited substances. South Australia has the broadest analogue provision, prohibiting any substances with substantially similar chemical structures, or substantially similar pharmacological effects.

With new ‘mimic drugs’ (ie those that mimic the effects of particular drugs while being structurally quite different from them), it may not be possible to know whether they have psychotropic properties or similar pharmacological effects to prohibited substances; testing of the substances may not yet have occurred, and research on the substances may not exist. Synthetic cannabinoid substances fall into the mimic category.

As noted in the quote from the MCCOC Report on Serious Drug Offences, above, vague references to similar pharmacological effects and similar terms lack determinate meaning and lend themselves to potentially varying expert opinions.

Some overseas jurisdictions have attempted to address the problems of analogues and synthetic drugs that are simply intended to have the same effect as prohibited drugs. Such approaches have created difficulties in those jurisdictions. Under the US *Federal Analog Act*, any chemical that is ‘substantially similar’ to a controlled substance can be treated as if it were also controlled, but only if it is intended for human consumption. This has resulted in mephedrone (banned in NSW under the analogue provisions) being legally sold as ‘bath salts’ and ‘plant food’ in those US states that have not taken steps to prohibit the substance at the state level. Similarly, a number of synthetic cannabinoids were initially discovered being sold as fertiliser in parts of Europe.

On the basis of the above an intent-based approach does not appear to have benefits over the existing fact-based approach under Schedule 1 of the DMTA.

Testing

The prescription and prohibition of drugs is not just a legal issue, but a technical one. Regardless of the approach taken to prohibit synthetic drugs, ultimately some degree of testing will need to take place to determine whether a substance meets the criteria set in the legislation for a prohibited substance.

Where a substance is specifically prescribed, testing is required to identify the substance. This is the case for all seizures falling under the DMTA and provisions exist to facilitate the admission into evidence of analysts' certificates. Where a substance falls under a broader analogue provision, testing may be more complex. For example, the existing analogue provision creates a two-limbed test: 1) psychotropic properties, and 2) structural similarity to a prescribed substance. Tests must be conducted to establish both limbs.

It is neither possible, nor desirable, to seek to prohibit classes of substances without some objective scientific tests that must be met. The challenge is to ensure that the tests set by the legislation are capable of being satisfied.

Framing the analogue provision

Related to the issue of legitimate use is the need to place appropriate boundaries on the breadth of any analogue provision. Each additional element which widens the potential range of substances captured by an analogue provision increases the risk that substances which have legitimate pharmaceutical or other uses might be captured.

Possible approaches to regulating synthetic cannabinoids in NSW

If the evidence establishes that synthetic cannabinoids fall outside the analogue provisions there are three options for consideration:

- Ad hoc prescription under Schedule 1 of the DMTA as new substances are developed
- Expand the analogue provision
- Add Therapeutic Goods Administration classes to Schedule 1 of the DMTA.

Ad hoc prescription under Schedule 1 of the DMTA as new substances are developed

While this approach does result in a window of opportunity during which new synthetic cannabinoids can be sold legally, it may provide the most certainty. It is also the prevailing drug enforcement strategy in Australia and jurisdictions around the world, and the reason why the DMTA specifically states that Schedule 1 may be amended by way of regulation, so as to allow new substances to be prescribed rapidly.

Expand the analogue provision

The possibility of removing the 'psychotropic properties' requirement from the analogue provisions was briefly considered by a DMTA Interagency Working Party in 2000. The view was expressed that a test beyond a mere similarity to a scheduled substance was necessary so as to avoid criminalising the possession of benign substances, and that the rapidity with which a substance could be added to Schedule 1 ameliorated concerns regarding the test. However, it is also noted that NSW appears to be the only Australian jurisdiction to include a psychotropic property requirement in its analogue provisions.

Removing the psychotropic element from the analogue provision may simplify the tests required to establish whether or not a substance falls under the analogue provision and reduce disputes between expert witnesses. It would not, however, address concerns regarding synthetic cannabinoids if they fall wholly outside the application of the analogue provision due to their significant structural difference to prescribed substances.

One solution to this problem may be to focus on the effect of the substances on specified receptors in the human brain. Synthetic cannabinoids work by activating cannabinoid receptors in the brain. A number of US jurisdictions have sought to ban synthetic cannabinoids by prohibiting substances which have a similar effect on cannabinoid receptors as THC.

Similarly to the existing application of the analogue provision, this approach does not require the substance to be added to Schedule 1 to make it illegal. It will be illegal if it has that effect, and there would be no “window of opportunity” for its legal supply. Testing would be required to show it has the requisite effect. This form of testing might be more complex or open to dispute.

Add Therapeutic Goods Administration classes to Schedule 1 of the DMTA

The Therapeutic Goods Administration (TGA) recently published the decision of the Delegate of the Secretary to the Department Of Health and Ageing for amendments to the SUSMP, who referred consideration of synthetic cannabinoids to the Advisory Committee on Medicines Scheduling (ACMS), in particular, whether they should be included in Schedule 8 or 9 of the SUSMP.

The ACMS recommended that the following groups of synthetic cannabinoids be included in Schedule 9 of the SUSMP:

- Benzoylindoles
- Cyclohexylphenols
- Dibenzopyrans
- Naphthoylindoles
- Naphthylmethylindoles
- Naphthoylpyrroles
- Naphthylmethyindenenes
- Phenylacetylindoles
- Synthetic cannabinomimetics

The ACMS noted that there were no currently known therapeutic uses for any of these groups of synthetic cannabinoids.

The group listing of “synthetic cannabinomimetics” is intended to make it explicitly clear that all synthetic cannabinoids (except where specifically listed) are to be considered Schedule 9 substances.

It is noted that the last term, “synthetic cannabinomimetics”, used by the ACMS is an outcome-based entry, that is, one that is based on the mechanism of action of synthetic cannabinoids as discussed above in relation to the effect of these

substances on cannabinoid receptors. If a similar term were to be adopted in the context of Schedule 1 of the DMTA, there would be a requirement on the prosecution to satisfy the court that a substance in question was, in fact, a synthetic cannabinomimetic.

The TGA has set an implementation date of 1 May 2012 for the updating of the SUSMP.

NSW agencies are currently considering whether and how restrictions along the lines proposed by the TGA can be implemented into NSW legislation (specifically, into Schedule 1 of the DMTA).

Other synthetic drugs

Police are also aware of other emerging synthetic drugs such as Methylenedioxypyrovalerone (MDPV) and Methylethcathinone (mephedrone or 4MMC). These substances are sometimes marketed as 'bath salts' with names such as 'Ivory Wave', 'Cloud Nine' or 'Vanilla Sky'.

As mentioned above, these substances appear to be captured by the analogue provisions of Schedule 1 of the DMTA, as they are structurally similar to the prohibited drug cathinone.