Submission No 23

INQUIRY INTO LAW REFORM ISSUES REGARDING SYNTHETIC DRUGS

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SUBMISSION BY

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TO

COMMITTEE ON LEGAL AFFAIRS

ABOUT

INQUIRY INTO LAW REFORM ISSUES REGARDING SYNTHETIC DRUGS

INTRODUCTION

- Stargate International ("Stargate") welcomes the opportunity to submit on the Legal Affairs Committee's Inquiry into Law Reform Issues Regarding Synthetic Drugs ("the Inquiry").
- 2 Stargate has been working with new psychoactives (or synthetic drugs) for approximately 15 years and is pleased to share its experience with the Committee, and to answer any questions the Committee may have.

SUMMARY AND RECOMMENDATIONS

3 Stargate considers that the most appropriate legislative response to the appearance of new psychoactives is the development of a testing and approval regime along the lines of the regime currently being developed in New Zealand.

New Psychoactives: a Challenge and an Opportunity

- 4 New psychoactives have risen to prominence in Australia over the last decade. The two most well-known examples are synthetic cannabinoid products and the various stimulants used in so-called "party pills", but there are many others easily available over the internet or in specialist retailers.
- The status quo is that new psychoactives are available to the public on an effectively unregulated basis **until** they are restricted or prohibited by various legislative instruments.
- It is clear that there is also a significant commercial demand for new psychoactives. New psychoactives are more attractive to members of the public than controlled drugs because they are cheaper, more easily available and do not attract the risk of prosecution. The experience in New Zealand has been that these drug alternatives displace prohibited drugs from the market and reduce the demand for prohibited drugs. This is desirable from a public health and law and order perspective.
- Stargate submits that new psychoactives pose a unique challenge to the public health system and require a unique regulatory response, because new psychoactives:
 - (a) Are often new compounds and their effects are not well understood;
 - (b) Can deliver psychoactive effects which are similar to those of controlled or prohibited substances;
 - (c) Can have very different risk profiles to the risk profile of the controlled or prohibited substance with the most similar psychoactive effect; and
 - (d) Can be easily substituted with other compounds that deliver similar effects.
- 8 Stargate acknowledges that there are legitimate health concerns around new psychoactives. There are a number of compounds which should not be available to the public, because they are toxic or because they have undesirable side effects.
- 9 But Stargate also submits that it is important to recognise that it does not follow that just because a particular new psychoactive has similar psychoactive effects to a prohibited substance, the new psychoactive is otherwise pharmacologically identical to that prohibited substance. Put simply, a synthetic cannabinoid does not necessarily raise the same health issues as cannabis just because it has a similar psychoactive effect.

What is therefore needed is an evidence-based approach which properly assesses and establishes controls on new psychoactives based on their health risks.

The Failure of Prohibition-Based Responses

- Prohibition has been an ineffective response to the challenge of new psychoactives, because banned psychoactives can be easily replaced by different compounds which deliver similar psychoactive effects. This will be the case no matter what legal mechanism is used to implement prohibition.
- New Zealand's experience with the temporary class drug notice regime created by the Misuse of Drugs Amendment Act 2011 illustrates this point. The regime allows the Minister of Health to ban the manufacture, import or sale of any compound or product with seven days' warning by notice in the New Zealand Gazette. This regime has failed to curb the availability of new psychoactives.
- A pre-emptive blanket ban would also be problematic. The risk is that such a ban would either be easily circumvented by further development of new psychoactives, or that it would be so broad that it would cover compounds with no recreational psychoactive use, but which would be useful in pharmaceutical or industrial compounds. Further, such a decision would be inconsistent with an evidence-based drug policy because it would control substances without an assessment of the risk of harm arising from their use.
- Ultimately, prohibition-based responses to the development of new psychoactives will lead to a reversion to black market controlled or prohibited drug use.

The Regulation of New Psychoactives in New Zealand

- Stargate submits that the only realistic response to the appearance of new psychoactives is the development of a testing and approval regime along the lines of the regime currently being developed in New Zealand.
- Such a regime prohibits the import, manufacture or sale of psychoactives **unless** they have been approved for sale by an independent regulator. Essentially, the approval criteria for sale require that a product be shown to have a low to minimal risk of harm before it is approved for sale. This evidence is obtained through pharmacological data and clinical trials.
- 17 As the New Zealand Government has recognised, a testing and approval regime will necessarily involve the approval for sale of psychoactive substances which meet the criteria set by the regulator. Such approved substances will be available for sale to the general public, albeit subject to controls.
- 18 The New Zealand Government considers that this option is preferable to a prohibitionbased response to the development of new psychoactives because legislation should not be used to prohibit substances which have not been proven to be harmful.

Stargate's Recommendations

- Stargate recommends that New South Wales adopt a regulatory regime based on the regime currently under development in New Zealand.
- The merits of such a regime in isolation are discussed above. But the implementation of such a regime in New Zealand also creates an opportunity for New South Wales to harmonise its regime with New Zealand, consistent with the Closer Economic Relations agreement and the trend towards trans-Tasman harmonisation.

IMPACT OF NEW PSYCHOACTIVES ON DEMAND FOR ILLICIT DRUGS

- There will always be a demand for psychoactive substances. From a public health perspective, the question is how best to channel this demand toward substances that pose the least risk and which cause the least harm.
- 22 Stargate submits that the New Zealand experience shows that safer drug alternatives have a significant competitive advantage over prohibited drugs in the general market for psychoactives, because they can be purchased and used with lower health and enforcement risk. It follows that regulation of new psychoactives is a valid harm reduction policy because it reduces the demand for and consumption of prohibited drugs.
- For example, a study carried out in New Zealand in 2006 before BZP/TFMPP-based products were banned found that 45.6% of BZP/TFMPP consumers mainly used party pills to avoid using illegal drugs, and 44.1% of BZP/TFMPP consumers used fewer illegal drugs since starting to use party pills.¹
- 24 Further evidence of the substitution effect of new psychoactives in New Zealand can be seen from the price of prohibited drugs when faced with competition from new psychoactives²:
 - (a) The reported average street price of cannabis in New Zealand failed to keep pace with inflation between 2006 and 2011 approximately the same time as synthetic cannabis products were starting to appear in the market;
 - (b) The reported average street price of MDMA in New Zealand declined constantly between 2006 and 2011 during which time legal alternatives such as BZP, DMAA and other new psychoactives entered the market; and
 - (c) The price of methamphetamine collapsed during 2005 and 2006, and did not recover until its principal competitor BZP was banned.
- It is well-established that the principle beneficiaries of the illegal drug market are organised crime groups. It follows that the development of a regulated market in new psychoactives, through the follow-on effect on the price of illicit drugs, are an important law and order tool.
- But the development of a regulated market in new psychoactives is also beneficial from a public health perspective. In principle, prohibited drugs are prohibited because they are dangerous. It would be desirable from a public health perspective if users could be persuaded to use new psychoactives that deliver similar effects without the associated health risks.
- A regulated market also reduces the opportunities for risky drug-related behaviour.

 Prohibited and/or unregulated drugs are often sold as powders for insufflation or for

Wilkins, C., Girling, M., Sweetsur, P., Huckle, T. and Huakau, J. (2006) Legal party pill use in New Zealand: Prevalence of use, availability, health harms and 'gateway effects' of benzylpiperazine (BZP) and trifluorophenylmethylpiperazine (TFMPP). June. Auckland: Centre for Social and Health Outcomes Research and Evaluation (SHORE), Massey University

Wilkins, C., Sweetsur, P., Smart, B., Warne, C., Jawalkar, S. (2012) Recent trends in illegal drug use in New Zealand: findings form the 2006, 2007, 2009, 2009, 2010 and 2011 Illicit Drug Monitoring System, Auckland: Centre for Social and Health Outcomes Research and Evaluation (SHORE), Massey University

- injection. This increases the chance of overdose or infection. Compounds such as BZP and DMAA have become more available in these forms since they were banned in New Zealand.
- 28 But there is no evidence that these riskier forms of drug supply are of themselves particularly appealing to consumers, such that they would choose an illicit drug presented in this way over regulated new psychoactives. Controls could be imposed on a regulated drug market to prevent risky forms of drug supply.
- There are also no controls on the quality or purity of illicit drugs. It is well-established that many "street drugs" are adulterated with other compounds which can be more toxic than the original drugs³. This makes treatment of complications more difficult. On the contrary, a regulated drug market would ensure that consumers knew what they had consumed and could advise health professionals accordingly.

FAILURE OF PROHIBITION-BASED RESPONSES

- This submission does not specifically address the failure of prohibition-based drug policy in general. But it is clear that prohibition-based responses to new psychoactives in particular have failed to curb the availability of such products.
- The starting point is that prohibition-based responses are rarely based on clinical evidence of health risks. Many substances appear to have been banned because they deliver similar psychoactive effects to prohibited substances, or on the basis of negative media coverage.
- To date, prohibition-based responses to the development of new psychoactives have been limited to banning particular compounds or products after they have entered the market by legislation or regulation. For example, the Misuse of Drugs Amendment Act 2011 enabled the Minister of Health to prohibit the import, manufacture, or sale of any compound or product by notice in the *New Zealand Gazette*. Other Australasian jurisdictions have adopted or about to adopt similar measures.
- This regulatory response has essentially been **reactive**, rather than proactive. New psychoactives are not banned until:
 - (a) The regulatory authority becomes aware that a product containing the new psychoactive is available; and
 - (b) The regulatory authority can identify the new psychoactive; and
 - (c) The regulatory authority can enact the necessary instrument to ban the sale of the psychoactive.
- As a result, attempts to control access to new psychoactives through prohibition have failed. While a large number of psychoactive compounds have been banned under various legislative instruments in Australia and New Zealand and elsewhere, new, unregulated psychoactives continue to appear on the market in large quantities. There has been no effective break in the supply of such substances to the public.
- For example, the prohibition on the sale of napthoylindoles in the United Kingdom (because they are treated as analogues of tetrahydrocannabinol) along with thousands of other substances covered by the analogue provisions, led to the appearance of new

³ See, for example, Wilkins, C., Sweetsur, P., Smart, B., Warne, C., Jawalkar, S. (2012) Recent trends in illegal drug use in New Zealand:

- synthetic cannabinoids such as AM-679, AM-1220 and AM-2201 on United Kingdom markets within weeks.
- This state of affairs could, in principle, persist almost indefinitely, given the number of new psychoactives potentially available. But Stargate does not consider that this would be in the public interest. The *status quo* incentivises the rapid development and sale of psychoactives with poorly understood health impacts.
- 37 Stargate notes that some Australian jurisdictions are now considering the implementation of pre-emptive blanket bans on new psychoactives. Stargate considers that this response is equally likely to fail, because:
 - (a) If the definition of compounds that are covered is not wide enough, manufacturers will simply switch to products which are covered; and
 - (b) If the definition of compounds that are covered is too wide, then compounds will be prohibited which would never be marketed as psychoactives but might well have other uses.
- 38 Stargate also considers that a pre-emptive blanket ban would be poor public policy, as it would control a range of psychoactives without providing for an assessment of their effects or health risks.
- 39 Finally, prohibition of new psychoactives is not likely to be any more effective than the prohibition of currently controlled drugs at preventing the importation and use of such compounds. The difference will be that the market would instead be controlled by criminals.

NEW ZEALAND'S REGULATION OF NEW PSYCHOACTIVES

The development of new psychoactives has posed similar issues for regulators in New Zealand. New Zealand has chosen to regulate new psychoactives rather than attempt to prohibit their sale entirely. Importantly, the New Zealand Government has confirmed that it is intended that products which meet safety criteria will be approved for sale.

New Zealand's Regulatory Regime

- The details of the new regulatory regime are still in the process of being finalised, with legislation due to be enacted by the end of August 2013. There is likely to be a transitional period.
- 42 However, the key features of that regime will be:
 - (a) The manufacture, importation or sale of "unapproved substances" will be prohibited and will attract penalties;
 - (b) An independent regulator established inside the Ministry of Health will be able to approve a substance for sale after:
 - Receiving acute toxicity, repeat dose toxicity, pharmacokinetics and genotoxicity data which illustrates that the substance is safe to proceed to human testing; and
 - (ii) Reviewing behavioural data from human clinical trials about the effects of the substance on physical and mental health and signs of dependence, withdrawal or aggression in users of the substance;
 - (c) The costs of testing will fall on the person seeking approval to manufacture or import a new psychoactive;

- (d) Approved substances will be subject to controls on how the products are packaged, who they can be sold to, and where they may be sold, as follows:
 - (i) All approved products will be restricted to over 18 year olds;
 - (ii) Packaging must be tamper-proof and include ingredients and required safety information;
 - (iii) Products must not be sold from on-licences (but off-licences will be able to sell approved substances), petrol stations, mobile premises, places where minors gather; and dairies and general grocery stores; and
- (e) Extensive controls on advertising:
 - advertising products approved under the regime will be prohibited except at the point of sale, either within premises where they are sold or supplied, or on internet sites from which they are sold or supplied;
 - (ii) point of sale advertising should be confined to material that communicates objective product information, including the characteristics of the product, the manner of its production, and its price. This restriction should also apply to advertising on websites selling these products;
 - (iii) advertising must not contain themes that are particularly appealing to children:
 - (iv) promotion of psychoactive substances, including sponsorship, will be prohibited in all media;
 - incentives to encourage people to purchase approved products, such as promotional gifts or free-of-charge supply by retailers, will be prohibited; and
 - (vi) advertising or promotion must not convey that the product is safe;
- 43 Stargate considers that this regulatory model, which was first proposed by the New Zealand Law Commission in its *Review of the Misuse of Drugs Act 1975* is a pragmatic and realistic approach to the development of new psychoactives.
- Regulating the sale of new psychoactives allows the Government to exercise control over a market which has to date been almost wholly unregulated. Attempts at controlling psychoactives through prohibition have simply driven manufacturers and consumers underground and accentuated the public health impacts of drug use. A regulated market in new psychoactives enables the Government to exercise a level of control over drug markets which has not hitherto been possible.
- A regulated market in new psychoactives will also deliver other public health benefits. Stargate's experience in New Zealand, and the most recent Illicit Drug Monitoring System report prepared by New Zealand's Massey University, show that users of prohibited drugs prefer to use legal highs where they are available. In short, legal substances have a significant competitive advantage over prohibited drugs, because users do not risk criminal conviction by using legal highs and most users have no wish to associate with or support criminal activity.

Implications for Australia

- As set out above, the introduction of a regulatory regime for new psychoactives in New South Wales would be justified on its own merits, because it is the most pragmatic response to the development of such substances.
- 47 However, the proposed implementation by New Zealand of such a regime strengthens the argument for the parallel implementation of a similar regime by New South Wales. It is in the public interest for New Zealand and Australia to harmonise, where possible, their regulatory regimes. Given that New Zealand is yet to implement its regulatory regime for new psychoactives, there is an opportunity for the early development of an aligned regulatory regime in New South Wales.
- As discussed if above, New South Wales persists in a prohibition-based regulatory response to new psychoactives, this approach is likely to fail, independent of developments in New Zealand. But the development of a regulated drug market in New Zealand will inevitably have flow-on effects for Australia, as New Zealand's closest neighbour. At the very least, it is likely to lead to an increase in the rate at which new psychoactives appear in New South Wales.
- But inconsistent regulatory regimes would also potentially raise issues for New South Wales authorities under the Trans-Tasman Mutual Recognition Act, and would be inconsistent with the trend towards harmonised regulation of pharmacologically active products. This would be inefficient and undesirable from a public policy perspective.