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'Legal highs'

The challenge of new psychoactive substances

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This paper aims to set out some of the policy and public health issues raised by the appearance of a wide range of emergent psychoactive substances of diverse origin, effect and risk profile (commonly referred to as 'legal highs').

It will start by considering what is meant by the term 'legal highs' and consider the historical context that has framed their appearance and must inform any response. It will then consider some of the approaches that have been adopted by different nations to control their availability and associated harms, including a preliminary assessment of their consequences, both intended and not.

To date, the approaches to regulation have varied between nations, both with respect to the nature and specificity of the measures taken and their intended outcome. Such diversity appropriately reflects the marked differences in the existing drug use problems and public health approaches to addressing such issues between nations.

WHAT IS A LEGAL HIGH?

Over the last decade the term 'legal high' has become an accepted addition to media parlance and a lay reference point for discussion among the general public in their consideration of issues related to drug use. However, when critically considered, the term is often misleading and factually inaccurate. 'Legal high' is a catch term that



KEY POINTS

- Evidence shows that alternatives to criminalisation exist that attain many desirable outcomes for governments, whilst minimising the unnecessary consequences of criminalising the individual user.
- While new psychoactive substances pose a challenge to existing drug control regimes, their appearance provides an opportunity to consider the trial of alternative policy and legislative approaches to drug control.
- An objective evaluation based upon scientific evidence is required to evaluate the utility of these different control options, as well as their impact on public health outcomes.
- Policy makers should not only reflect on the unintended consequences of drug prohibition but also the current and historical failures of the adequate regulation of the legal markets for alcohol and tobacco, and for pharmaceuticals.

has historically referred to a diverse group of naturally occurring and novel synthetic compounds whose consumption results in widely differing effect and risk profiles.³ They have also been variously referred to as ‘designer drugs’, ‘herbal highs’, ‘synthetic drugs’ and more recently ‘research chemicals’.

Because the definition is so broad and the legal status (and availability) of the substances are constantly changing, there is no definitive list of legal highs. Substances which have at one time or another been considered to fall under this term have included traditional plant-based products, often with a long and culturally sanctioned history of human consumption, such as herbs (e.g. *salvia divinorum* and kratom), seeds (e.g. baby Hawaiian woodrose), fungi (e.g. magic mushrooms, fly agaric) and cacti (e.g. peyote). More recently these ‘ethnobotanicals’ have been joined by a dizzying array of new synthetic compounds including the cannabinoid receptor agonists (such as JHW-018 and others found in herbal smoking blends such as the ‘Spice’ products),⁴ cathinones (such as mephedrone, 4-methylmethcathionine)⁵ and the piperazines (such as benzylpiperazine (BZP)).⁶

The increase in notifications of new psychoactive substances to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) has risen from an average of five per year between 2000 and 2005 to over 40 in 2010.⁷ The number of new classes of untested drugs and variations on molecular structure that may be waiting in various laboratories around the world is daunting. In the UK alone, the last two years has seen more than five separate additions totalling more than 50 different compounds to the Misuse of Drugs Act. This represents more legislative additions than in the last two decades put together.

While recent media and policy interest may suggest that the idea of promoting substances whose development, rediscovery

and/or manufacture have the explicit aim of circumventing legislative restrictions is a recent phenomenon, the truth is many have been available for several decades. What has changed is not only the diversity and potency of the products but their widespread promotion and distribution not only through the internet and expected suppliers such as “head-shops” but also local corner shops, grocery and DVD rental stores. The development of global web-based marketing and distribution distinct from illicit street markets seriously limits the utility of existing supply reduction strategies.⁸ Taken in combination with the rapid increase in openly public marketing nations, politicians and legislators have been forced to reflect upon and update their responses.

By lumping substances with diverse effect and risk profiles that appear at different points in time together, policy makers find themselves in the unenviable position of being pressured to make quick decisions about the risks of harm often based on no more than unverified media speculation and uncertain extrapolation from scientific knowledge on related chemical structures. Although the precautionary principle is used to support pre-emptive legislative control, the reality is that while such actions may remove harmful substances from widespread circulation they are rapidly replaced by other equally unfamiliar molecules that may or may not share a similar risk effect and risk profile.

Such substances like their predecessors “parachute” into communities bypassing traditional social networks that often provided some opportunity for people to learn about a new drug in close proximity to friends. Thus when considering which approach to supply control is most effective with respect to these new substances, it is worth reflecting upon what gains are made and what potential avenues for optimising public health are lost when control through drug legislation is adopted as opposed to other forms of supply control.

THE HISTORICAL CONTEXT WITHIN WHICH THESE DRUGS HAVE APPEARED

As noted above psychoactive substances that avoid regulation have been promoted, developed and marketed for decades. What has changed in recent years has not only been their diversity and potency but perhaps most importantly the globalisation of drug markets through the internet – truly a drug market without borders. The opening up of the global market place has coincided with a significant disruption in the international supply of MDMA over recent years.

The decline in the supply of MDMA is thought to be largely the result of global disruptions to the illicit supply of key MDMA precursor chemicals.⁹ Pharmacological analysis of so called ‘ecstasy’ pills in a number of countries around the world has revealed they often contain substances other than, or in addition to, MDMA including caffeine, methamphetamine, piperazines and sometimes ketamine.¹⁰ Up to half of ‘ecstasy’ seizures made in the Netherlands in 2009 were found to contain no MDMA; rather the pills contained mCPP (meta-Chlorophenylpiperazine) and mephedrone (methylmethcathinone) or another psychoactive substance.¹¹

These findings are mirrored by user reports on the perceived quality of ecstasy pills. In the 2009/10 Mixmag Survey, 76% of almost 2000 users believed that the quality of MDMA pills had reduced, with 68% reporting a decline in 2010/11.¹² Further afield in New Zealand, ‘ecstasy’ tablets seized by the authorities have also been found to contain BZP (benzylpiperazine), MDPV (methylenedioxypropylpiperazine), mephedrone and methylone (methylenedioxypropylmethcathinone).¹³ Taken in conjunction with the wide unrestricted availability of other uncontrolled precursors (such as mephedrone’s precursor 4, methyl-propionphenone) the falling availability of MDMA may have encouraged drug manufacturers and dealers to consider other compounds which have similar ‘ecstasy’ like appeal,

which could be used both as substitutes for MDMA in ecstasy pills and also for sale in their own right. This shift in what is being produced has been accompanied by a shift in the location of manufacture from Europe to other regions, notably South East Asia¹⁴ and the burgeoning economies of India and China with relatively poorly regulated control mechanisms.

Why the UK in particular may have been such a ripe market for emergent synthetic drugs such as mephedrone is uncertain. It may have had something to do with the fact that the marked reduction in the availability of MDMA coincided with a sharp fall in the purity of cocaine.¹⁵ Taken together, dissatisfaction with the existing illicit market would have set the appropriate (receptive and cash rich) market conditions for synthetic stimulants such as the cathinones and piperazines.¹⁶ With subjective effects similar to MDMA and cocaine¹⁷ it is of note that evidence from the Netherlands suggests that mephedrone has found its way into tablets being sold as MDMA.¹⁸

It may also be possible that users chose these substances because they considered them better value for money and a more consistent product.¹⁹ The wide availability and promotion of synthetic cannabinoids has not, however, occurred in such a quality vacuum, with high quality cannabis being widely available across Europe. One might speculate that decades of health promotion, warning of the risks of traditional illicit drugs including cannabis has perhaps encouraged some to seek alternative cannabis preparations.

Certainly, legal high producers have exploited health and product quality concerns claiming that expansion of their market reduces the size of the illicit drug market by providing a legal ‘safer’ alternative to illicit drugs. However attractive this proposition may be, there is no evidence to support it. Indeed it is just as plausible that the use of legal highs could act as a gateway into drug use at age where access to traditional illicit

may be less easy, and could subsequently promote interest in more expansive drug taking.

LEGISLATIVE BACKGROUND OF DRUG CONTROL AND EMERGENT DRUGS

Historical responses to psychoactive drugs, based on long standing international legislation and conventions, have set the tone and provided guidance to individual nations on how to legislate and cooperate on matters relating to illicit drugs such as cannabis, cocaine and heroin. Often these were considered as reflective processes conceived in the mid-20th century, informed over time by a collective body of knowledge drawn from the social and scientific academic communities and to a lesser extent those who used the substances. Although many will disagree and argue that international politics prevailed over scientific evidence for political reasons, historically psychoactive substances were brought under some sort of legal control because nations were concerned that their unregulated use and trade posed a significant risk for individual and/or public health. While we accept there are many other, often less legitimate, reasons why some nations have sought to control drugs in their own and distant shores, the desire to protect the health of one's population will no doubt have featured significantly in the debate.

However, the rapid appearance of many drugs with little or no history of human consumption and a paucity of scientific research mean that such informed debate is no longer possible. As such, nations must decide whether the existing systems for assessing risk and putting new substances under international control are fit for purpose. Currently the concern is that, in automatically turning to existing legislation and structures, governments are relying on rushed and inadequately informed scientific committees to make decisions under pressure from political and media panics.

They may also be missing the chance to consider alternative approaches which are currently being called for by nations and senior policy making bodies.

RESPONSES SO FAR: EUROPE AND NEW ZEALAND (see Table 1)

The responses to novel psychoactive substances have varied from default criminalisation to control under consumer protection (where the producers must prove safety of their product) or medicines law (where possession for personal use is not a crime) and this reflects the disparate existing drug markets and controls between countries. While the approaches and the collateral harms are different, the basic objective of reducing availability (supply reduction) remains the same. Perhaps what differentiates recent approaches has been an explicit desire by some nations to avoid criminalising individual users. While the debate and legislation to date is worth reviewing, there has been insufficient experience as of yet to suggest one form of control may have merit over another across a wide number of territories.

Given that the growth of new psychoactive substances has been more marked in Europe than anywhere else, a useful place to start this review is consider the current assessment framework that has been adopted across Europe to analyse the potential risks posed by new substances. The immediate challenge is that new substances can be hard to identify, given their speed of appearance, diverse branding and inconsistent batch/product composition. Their short history of use and limited scientific study mean they possess unknown toxicity, abuse liability and risks associated with long term use. In 2005 a new EU-wide system on the information exchange (utilising national early warning systems), risk assessment and control of new psychoactive substances was adopted.²⁰ Member states have found this process useful though the

Table 1: Initial (and subsequent) controls for novel psychoactive substances across the EU

	<i>Consumer Protection</i>	<i>Medicines Act</i>	<i>Misuse of Drugs Act</i>
<i>Mephedrone</i>	Poland(1) UK	Finland Netherlands	Should be all EU countries as of 9 December 2011 following EU Council Decision 2010/759/EU one year previously. Not yet reported as controlled under drugs laws by Netherlands, Finland, Portugal.
<i>Synthetic Cannabinoids</i>	Poland(1) Italy	UK Germany Austria Hungary (2)	Bulgaria, Croatia, Czech Republic, Denmark, Estonia, France, Germany, Ireland, Latvia, Lithuania, Luxembourg, Poland, Romania, Sweden, UK
<i>BZP</i>	Poland?(1)	Spain Netherlands Norway UK	Should be all EU countries as of 8 March 2009 following EU Council Decision 2008/206/JHA one year previously. Not yet reported as controlled under drugs laws by Netherlands

(1) Poland effectively used consumer protection laws (State Health Inspectorate) against “head shops” in October 2010 – these were selling many different products.

(2) In Hungary, a Formal Decision was announced by the Regional Chief Medical Officer on behalf of the Central Hungarian Regional Institute of National Public Health and Medical Officer’s Service to prohibit one company’s distribution of named herbal mixtures (it is not an overall prohibition).

The authors would like to thank Brendan Hughes of the EMCDDA for his help in the production of this table

capacity to detect new substances varies widely between member states.

The process has adopted a systematic, albeit lengthy and bureaucratic response, to the appearance of novel psychoactive substances. Notification of a new substance is followed by an initial scoping exercise by Europol and the EMCDDA, which, if deemed necessary, prompts a risk assessment from the EMCDDA. Based on its report, the European Union Council and Commission determine whether to submit the substance to control measures. Submission to control measures means that member states are required to introduce criminal sanctions. Such a process has been followed twice, in the cases of BZP and mephedrone.²¹

Few would disagree with the idea that a newly emergent drug that displayed overt toxicity and significant risk harm should be subject to emergency banning. However the European Commission itself acknowledges that ‘risk assessments are inherently based on partial knowledge’ and that in the case of mephedrone and BZP ‘there was limited scientific evidence on the acute and long term-effects on health and fatalities, on consumption patterns and on prevalence’. In the absence of clear evidence, government decisions affected by media coverage will often wish to appear tough on these substances. However, the EU Council also acknowledges ‘the public health threat from new psychoactive substances might appear to be less than that of traditional illicit drugs’.²² The framework for risk as-

assessment is therefore a good first step. Nonetheless, in isolation from a broadening in responses and the capacity to determine the impact of legislation on availability and public health harms related to new and old drugs, it falls short of a comprehensive solution. In keeping with this, a recent survey has identified that a large number of member states do not consider criminalisation ‘as always a sustainable and [*swift enough*] option for tackling the spread of new psychoactive substances’ and want other approaches, such as temporary control orders, to be considered.²³

Given the delay between identification, assessment and action, many are calling for the adoption of swifter responses that can be reviewed in time. For example, temporary banning orders using a variety of legislative frameworks may be an effective approach to remove a product before it has the chance to result in significant harm. As stated by Hughes and Winstock, ‘following rapid control, should an unhurried risk assessment then determine that a compound has a low acute toxicity (aside from short term behavioural risks associated with any form of intoxication), various approaches other than the drug control laws could also be considered, minimising any unintended harms arising from criminalisation of the user and ensuring efficient use of law enforcement resources’.²⁴

It is unfortunate that it is difficult to foresee any government announcing that, following a risk assessment it had decided to remove a novel psychoactive substance from a controlled list and would now make it available for regulated purchase through approved sales outlets. It can be argued that an optimal public health response should at least consider the consequences of allowing a drug with a potentially safer profile to be regulated instead of simply observing the displacement of interested users to a newer and even less profiled substance.

What follows is a brief description of some of the key approaches adopted across the European Union,²⁵ where the potential for harmonisation of legislation holds the promise of swift, proportionate and uniform responses; and in New Zealand, where a long history of experiencing the problems of legal highs has resulted in a review of national drug laws. What differentiates the approaches is not only the type of legislation adopted (drugs law v. consumer protection) and the focus of its attention (individual consumer v. supplier) but also the speed of response and bureaucratic complexity utilised.

One such example is the use of basic consumer and health protection laws which can be adopted for goods not covered elsewhere. Encompassing issues as diverse as product characteristics, labelling and instructions for use, consumer and health protection laws state that a product should not present any (or only minimal) risks under reasonably foreseeable conditions of use. Their practical application was used last year when the State Sanitary Inspectorate closed over 1,000 head shops in Poland in October 2010.²⁶ Although not criminalising users, this blanket approach outlawed the sales of all ‘legal highs’ together, not just the few where there were serious health concerns. In another less drastic example, the failure to label Spice products in Italy led to confiscation of the product due to labelling contraventions.²⁷

Other possibilities exist, such as the adoption of food regulation or even cosmetic and fertilizer legislation. One commonly adopted approach has been to declare a new psychoactive product as a medicine, requiring it to have marketing authorisation which, if withheld, means that the product cannot be marketed or supplied. Such an approach can be adopted swiftly using existing national legislation and does not require presumptive risk assessments on limited scientific data. For example the banning of the import and supply of Spice

products using medicines legislations was adopted to avoid criminalising users in Austria and led to the rapid cessation of their open sale.²⁸ This would suggest that the sanction of a regulatory fine, without the threat of prison, was a sufficient deterrent for most suppliers.

THE NEW ZEALAND LAW COMMISSION RECOMMENDATIONS FOR NEW PSYCHOACTIVE SUBSTANCES

A large market for BZP ‘legal highs’ operated in New Zealand from the early to the mid-2000s. As many as 24 million BZP ‘legal high’ pills had been sold in New Zealand by 2004, and the BZP industry was estimated to generate retail sales worth US\$ 30-35 million per year.²⁹ A national household survey of BZP use in New Zealand conducted in 2006 found that 15% of the population aged 13-45 years old had used a ‘legal high’ containing BZP in the previous 12 months, including 40% of males aged 18-24 years old.³⁰

The manufacture and sale of BZP party pills remained entirely unregulated in New Zealand in the early 2000s as BZP did not easily fit into the existing regulatory control regimes for foods, dietary supplements, hazardous substances or dangerous recreational drugs.³¹ The New Zealand Government commissioned a number of research studies of BZP legal highs over the following two to three years to inform their legislative response. In the meantime, entrepreneurs selling BZP legal highs attempted to establish their own industry self-regulation but with fairly limited effectiveness.³²

The findings from the Government commissioned research indicated that BZP legal highs were associated with a number of health risks and negative social consequences.³³ As a result, the New Zealand Government announced its intention to prohibit BZP in 2007, with the ban coming into effect in April 2008.

One of the political outcomes which emerged from the decision to prohibit BZP

Table 2: Other options for control

- Unrestricted sale*
- Legal sale with age, place of sale and advertising restrictions
- Government monopoly sale (e.g.. sale of alcohol in Sweden, Norway and Finland)
- Pharmacy only sale (over-the-counter pharmacist sales)
- Prescription only access
- Restricted sale without medical supervision*
- Restricted sale with medical supervision*
- Prohibition with civil penalties (i.e. fines)
- Prohibition with diversion and education options
- Prohibition with criminal penalties

* see Hughes and Winstock *In press* for in depth descriptions

was an undertaking that the New Zealand Law Commission would conduct a comprehensive first principle review of New Zealand’s *Misuse of Drugs Act 1975* (MODA). The review was intended to determine whether MODA was fit for the purpose of controlling drug use in the 21st century, and in particular for dealing with new psychoactive substances such as BZP.³⁴

THE LAW COMMISSION REVIEW

The Law Commission acknowledged that the prohibition of BZP had not solved the problem of legal highs in New Zealand.³⁵ A new wave of ‘non-BZP party pills’ containing DMAA had quickly replaced BZP and were subsequently sold from the same retail network. Furthermore, like BZP before its ban, DMAA was not covered by any existing regulatory control regime. The Law Commission pointed out that under the present system there were often significant time delays before a substance could be appropriately controlled, as government officials needed time to gather evidence that the new psychoactive substance was

Table 3: Criteria to support the sale a novel psychoactive substance

1. The nature of the harm caused by the substance (including its prevalence of use) and any benefits from its use;
2. Whether the harm of the substance can be effectively mitigated by the imposition of regulatory controls;
3. Likely consequences of any proposed regulation or prohibition of the substance (i.e. assessing alternative regulatory approaches) ; and
4. Any possible displacement effects that might occur because of the way other substances are regulated (i.e. the risk prohibition might encourage the use of a more harmful substance)

harmful, and further time was required before legislation scheduling a harmful substance under MODA could be passed into law. During this time, the new psychoactive substance was marketed and sold without restriction and considerable money could be made by entrepreneurs involved in its sale.³⁶ The Law Commission considered existing regulatory regimes for hazardous substances, for foods, and dietary supplements to be inappropriate to control the new psychoactive substances. They concluded that a new regulatory regime was required to address the unique risks of new psychoactive substances intended for recreational consumption.

The new regulatory framework proposed by the Law Commission would require those wishing to sell a new psychoactive substance to demonstrate its safety *before* it could be manufactured, imported and sold. This was the approach advocated by most of those who were consulted by the Law Commission during the review process.³⁷ The new regime would apply to all psychoactive substances which were not considered harmful enough to be classified under MODA and would be administered by its own separate regulatory body. The Law Commission outlined four criteria (see Table 3) to determine whether a psychoactive substance should be issued an approval for sale under the regime.³⁸

TYPES OF REGULATION

The Law Commission suggested that generic statutory controls should be

imposed on new psychoactive substances which could then be tailored to substance-specific controls by the regulator. The restrictions they recommend should be considered are outlined in Table 4.

ANALOGUE LAWS

Faced with the enormous number of compounds within a single chemical class, legislators are being reasonably tempted by the use of analogue laws. Broadly speaking, the term ‘analogue’ refers to a compound which shares a major chemical structure in common with another. For the organic chemist, however, the term analogue is used to describe compounds that differ only by replacement of one atom or a simple functional group for another. Such laws have recently been adopted in the UK to control a group of synthetic cathinones (mephedrone, methylone and butylone) and have recently been used in Israel and Japan.

The adoption of ever more sophisticated chemical laws have led to scientific debate within court rooms in countries such as Israel where definitions of what constitutes an ester are argued by government and psychoactive chemists. The terms can also be used more broadly to pre-empt the appearance of novel drugs with potential psychoactive effects.³⁹ The United States Federal Analogue Act of 1986 defines an analogue as a substance which is *substantially similar* (not defined) to an already controlled substance and has or is *thought to have an effect* (not defined) similar or greater to that substance.

Table 4: Restrictions to be considered on the sale of new psychoactive substances

1. Age of purchase – same as alcohol (i.e. either 18 or 20 years old);
2. Advertising and promotion – prohibited except within the premises at point of sale or from internet site where they are sold (including sponsorship);
3. Places of sale – prohibited from places where alcohol is sold, petrol stations, pharmacies, non-fixed premises and places where children gather (e.g. schools). A particular concern was discouraging use with alcohol and in combination with driving;
4. Prohibition of giving free samples of products as part of promotional campaigns;
5. Restrictions on who can sell products – those convicted of a drug dealing offence in the past five years not permitted to manufacture or sell new psychoactive substances (i.e. to encourage separation from illegal drugs market);
6. Packaging and labelling requirements – child proof containers, accurate labelling of ingredients, health warnings, recommended dosage level, and the phone number of National Poisons Centre;
7. Manufacture standards imposed and enforced;
8. Price controls – an excise tax similar to alcohol and tobacco imposed;
9. Enforcement agency with appropriate powers of entry and search established;
10. Offences and penalties stipulated.

Analogue laws such as these are blunt tools that leave chemists little option but to explore structures that are even less familiar. Such laws not only lump together substances that have widely differing effects, profiles and toxicities but also run the risk of prohibiting entirely harmless substances and thereby impacting upon existing manufacture processes or limiting the number of compounds available for future research and development. Identifying the precise chemical structure of compounds requires considerable expertise and is also financially costly and this can be an issue for countries with limited public funds. However, analogue laws were judged by the New Zealand Law Commission to have been ‘reasonably effective’ in New Zealand in recent years.⁴⁰

UNWANTED CONSEQUENCES OF CRIMINAL CONTROL (see Table 5)

In considering what the unintended consequences of any new drug legislation, it is important to be clear about what the objec-

tive of the law was. This may seem too obvious a question to ask. However, the explicit aim beyond reducing availability and consumption is sometimes not considered at all, with issues of enforceability and downstream unintended consequences being given scant attention either before or after the law is passed. Table 5 highlights some of unintended consequences of control under drugs laws.

In the absence of a systematic framework for a comparable assessment of the impact of different drug laws (taking into account the compounding factors of pre-existing drug use prevalence, illicit markets and enforcement variables) it is not possible to be certain about the extent to which each of these unintended consequences may arise. However, given that one consistent unhelpful consequence is the potential criminalisation of young people for the possession of small amounts of drugs, it is desirable that other approaches to control that may reduce availability and problematic users be considered.

Box 1: Inconsistencies within the international drug control system

The Global Commission on Drug Policy, composed of eminent high-level political figures, ‘encourage[d] experimentation by governments with models of legal regulation of drugs’ and recommended that ‘national authorities and the UN need to review the scheduling of different substances’.⁴¹

Providing expert advice on the scheduling of substances under the UN drug control conventions is mandated to the WHO. Different approaches under the 1961 and 1971 Convention, however, have led to numerous inconsistencies that the WHO has difficulty dealing with. The WHO Expert Committee on Drug Dependence confirmed that the ‘decision as to whether to control analgesic and stimulant drugs under the 1961 or 1971 Convention is a major problem’, because ‘the criteria for choosing between the two Conventions are ambiguous for these classes of drug’.⁴² Additionally, substances that were ‘convertible’ into so-called ‘psychotropic’ drugs were left out from the 1971 schedules, in contradiction to the logic applied to narcotic drugs under the Single Convention. Several of those ‘convertible substances’ were later included as ‘precursors’ in the lists of

the 1988 Trafficking Convention. Ephedrine, for example, is the main precursor for methamphetamine, controlled under the 1971 Convention, but appears in the precursor list of the 1988 Convention. Ephedra is the plant from which the alkaloid ephedrine can be extracted, similar to the extraction of cocaine from the coca leaf, but ephedra is not under international control.⁴³ The principal alkaloids of khat (cathinone/cathine) are scheduled under the 1971 Convention, but the raw plant materials – in contrast to coca leaf- again were never placed under international control.

Legal inconsistencies between the UN treaties thus allowed the growth of a variety of existing national regulations and the emergence of a ‘legal high’ distribution system for certain psychoactive plants. In recent years, the INCB has regularly overstepped its mandate by volunteering its advice to place certain psychoactive plants and substances under control, interfering with the treaty mandate specifically and uniquely given to the WHO.

Written by Martin Jelsma, from the Trans-national Institute

The suggestion that nations should look outside the box is being accepted at the highest levels. In its 2009 World Drug Report the UNODC acknowledged a range of unintentional and undesirable consequences of overzealous drug control. It recommended a reorientation of drug law enforcement to protect health and requested that enforcement agencies look beyond arrest and imprisonment and explore novel ways of disabling the market.⁴⁴ Similar calls for a review of existing scheduling processes, which appear to be inconsistent in many areas such as those relating to control of plant-based substances and the adoption of alternative approaches has recently been made by the Global Commission on Drug Policy (see Box 1).

There is also the apparent conflict between the UNODC⁴⁵ which recently encouraged governments to consider alternative approaches to drug control based on criminalisation, and the most recent report of the International Narcotics Control Board (INCB)⁴⁶ which urged countries to monitor the use of a whole range of traditional herbal stimulants and hallucinogens such as kratom, khat, salvia divinorum, etcetera, and advance them for scheduling under drugs legislation if concern merited. In the case of khat, for example, this contradicted the advice given by the World Health Organisation (WHO) expert committee concluding, after a review of khat, that it had found no reason to advise its placement on any of the schedules of controlled drugs.⁴⁷

Given the thousands of potentially marketable psychoactive compounds available, it is not surprising that control of one substance or group of substances is rapidly followed by the promotion of still legal yet highly effective alternatives. The list of replacement molecules is dauntingly long.⁴⁸ Though no substance yet seems to have captured the interest of the drug using market in the same way as mephedrone did, what is clear is that the absence of a clear contender has not stopped interest in the web-based market place. It is too early to determine whether serious organised crime has yet become involved in the remarketing and distribution of formerly legal highs.

In the absence of a systematic framework to assess the impact of legislation in different countries it is difficult to know what the impact of banning a drug is. While closing down smart shops will reduce high street availability and public promotion, the impact of legislation on reducing availability and use of internet sourced substances is less clear. Available data from the UK on the impact of the ban on mephedrone provides a mixed picture. A small follow up study of a clubbing sample conducted a few months after the ban suggested that there has been a migration of mephedrone distribution from the internet to street dealers, a doubling of price and a perceived fall in quality.⁴⁹

A larger follow up study conducted in collaboration with Mixmag⁵⁰ suggested a marked reduction in, or cessation of, mephedrone use in 40% of over 1,000 users, but also confirmed transition to the street dealing market, an increase in price, falling purity and an increase in the use of illicit stimulants by 20-30% of interviewed users. Although this sample is not representative of the general population but is rather a group of sentinel users with greater levels of drug use than the general population, they might be considered to be more aware of, and sensitive to, changes in drug availability as a result of legislative change.

This displacement back to traditional stimulants mirrors the suggestion put forward by Bird that the availability of mephedrone before it was banned in the UK may have contributed to the significant fall in deaths from cocaine and ecstasy in the first half of 2009.⁵¹ The wider data related to the impact of the mephedrone ban upon mortality-related issues remain unclear. This is especially important given that widely publicised deaths erroneously attributable to mephedrone were instrumental in the banning of mephedrone.

A personal communication from John Corkery (Programme Manager of the National Programme on Substance Abuse Deaths, based at St George's Hospital, University of London and Research Lead, School of Pharmacy, University of Hertfordshire, j.corkery@herts.ac.uk) suggests that while 'there is evidence to suggest that the number of alleged/suspected deaths did peak about the time of the ban, as did confirmed cases with positive post mortem toxicology results, deaths involving mephedrone were continuing into the summer of 2011. The point is that methcathinones are still around and causing deaths'.

However, death is not the only harm and certainly not the one most likely to impact on users or third parties. Perhaps more relevant are the shifting views of users who, with time, may become more aware of the drugs harms amongst themselves and those they care for. The study conducted with Mixmag in 2010/11⁵² highlighted that among people worried about their friend's use of drugs, mephedrone was the most common drug to cause concern.

Taken in conjunction with a study undertaken as part of the risk assessment,⁵³ it might be argued that the decision to control mephedrone, a drug with high abuse liability,⁵⁴ was the correct thing to do. The truth is that there is not enough robust evidence to analyse at present to come up with a clear answer.

Table 5: Unintended consequences of the prohibition of emergent psychoactive substances

<i>Wider drug market</i>	<i>Individual</i>	<i>Nation and its resources</i>
<ul style="list-style-type: none"> • Replacement by other new untested compounds • Transition of newly banned substances to the illicit street market with possible involvement of serious organised crime rings • Displacement to the substances within the pre-existing illicit market • Loss of analogues being investigated for therapeutic potential. 	<ul style="list-style-type: none"> • Criminalisation • Higher cost of substance* • Lower purity of outlaws substance with potential increase in health related harm • Necessary contact with dealers of other substances • Unregulated drug market • No possibility of consumer protection or quality control. <p><i>* This may be protective in the same way that taxation and price raises tend to reduce the consumption of tobacco and alcohol – the difference being in the latter case that the increase occurs through taxation with the possibility of money being utilised for public health purposes.</i></p>	<ul style="list-style-type: none"> • Increased resources for enforcement • Loss of possible taxable revenue • Uncertain credibility of new legislation passed with limited information • Increased burden upon over stretched law enforcement runs the risk of new laws never being effectively implemented.** <p><i>**control under laws will also rely upon enforcement by equally stretched agencies who may legitimately indicate they have other priorities.</i></p>

The absence of such an answer is unfortunate since there is the possibility that if harms associated with new psychoactive substances could be accurately identified and ranked⁵⁵ then users of psychoactive substances could be steered towards those with a better safety profile. In line with the concept of liberal paternalism, the market itself could be nudged to promote a selection of less dangerous drugs.

CONCLUSION

While new psychoactive substances pose a challenge to existing drug control regimes, their appearance provides an opportunity to consider the trial of novel policy and legislative approaches. The core aim of any drug control regime must be to protect individual and population well-being and health. It is increasingly recognised that there are unintended consequences associated with criminalisation as the primary approach for drug control. There are now

increasing calls for countries to adopt approaches that minimise these unwanted impacts.

At a time of fiscal restraint and competing public health priorities, the appearance of emergent psychoactive substances thus provide an opportunity to test alternative approaches to drug control. Completely novel approaches are ready to be explored. Many of these approaches sit comfortably within a world where those seeking to profit from the sale of a psychoactive drug would be required to pay for the research to establish its level of safety. Such an approach has now been enacted in Poland⁵⁶ and has been proposed in the new regulatory framework proposed by the New Zealand Law Commission.

An objective evaluation based upon scientific evidence is required to evaluate the utility of different control options. Countries wishing to trial new regulatory ap-

proaches should be supported to rigorously evaluate the impact of their legislation on public health outcomes. They should also be cautioned, because alternative approaches are, like the substances, often novel in their application and uncertain in their effect. Policy makers should not only reflect on the unintended consequences of drug prohibition but also the current and historical failures of the adequate regulation of the legal markets for alcohol and tobacco.⁵⁷

Similar lessons can be learnt from the pharmaceutical industry where proposed solutions ended up causing more harm than the problem they were trying to address as in the case of temezapam gel capsules being introduced to deter injecting.⁵⁸ The current high levels of alcohol related harm in many Western countries illustrate the difficulties of trying to regulate a legal drug market which is dominated by a wealthy and influential industry. The history of the tobacco industry demonstrates how legal drug companies are willing to continue to promote their products, even when they are aware of the serious health risks they pose to users in the pursuit of profit. Those advocating for a new legal high sector should reflect on why governments were unable to enforce appropriate regulatory regimes over these existing legal drugs.

Evidence to date suggests that alternatives to criminalisation exist that attain many of the desirable outcomes for governments whilst minimising the unnecessary consequences of criminalising the individual user. For many observers, 'it seems to be more efficient to enforce medicines or consumer laws against suppliers and distributors, than to prosecute many individual users under criminal drug laws'.⁵⁹

NOTES

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Drug Law Reform Project

The project aims to promote more humane, balanced, and effective drug laws. Decades of repressive drug policies have not reduced the scale of drug markets and have led instead to human rights violations, a crisis in the judicial and penitentiary systems, the consolidation of organized crime, and the marginalization of vulnerable drug users, drug couriers and growers of illicit crops. It is time for an honest discussion on effective drug policy that considers changes in both legislation and implementation.

This project aims to stimulate the debate around legislative reforms by highlighting good practices and lessons learned in areas such as decriminalization, proportionality of sentences, specific harm reduction measures, alternatives to incarceration, and scheduling criteria for different substances. It also aims to encourage a constructive dialogue amongst policy makers, multilateral agencies and civil society in order to shape evidence-based policies that are grounded in the principles of human rights, public health and harm reduction.



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