

NEW PSYCHOACTIVE SUBSTANCES REVIEW

REPORT OF THE EXPERT PANEL

September 2014

The views expressed in this report are those of The New Psychoactive Substances Review Expert Panel

Alternative format versions of this report are available on request from DrugsAlcoholSupport@homeoffice.gsi.gov.uk

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Chapter 1: Introduction

1. Background to the New Psychoactive Substances Review

In recent years, the United Kingdom has seen the emergence of new drugs that have similar effects to drugs that are internationally controlled. These drugs can be collectively called New Psychoactive Substances (NPS).

These drugs have been designed to evade drug laws, are widely available and have the potential to pose serious risks to public health and safety and can even be fatal. The Advisory Council on the Misuse of Drugs (ACMD) (the Government's independent statutory drug advisers) advise that the short-term harms of NPS can include paranoia, psychosis and seizures and that their long-term harms are often unknown. NPS are advertised and sold as 'legal highs', often under a variety of brand names, at low risk and significant reward for suppliers. There has been a rapid increase in the number and range of new substances with greater ease of availability, with their open sale in offline retail outlets¹ and through the global marketplace of the internet.

At a time when traditional drug use such as cannabis (Home Office, 2013) is declining, NPS pose a significant challenge to governments. The UK Government's response to date has been far reaching but it recognises that there is more to be done.

In December 2013, the Home Office appointed an expert panel (the Panel) to look at this issue and provide recommendations to the Government. The Panel members were drawn from a range of areas, including enforcement agencies and prosecuting authorities; local authorities; medical and social science experts; forensic science experts; and academia. In addition, other experts and interested parties, including those from government departments, devolved administrations, international administrations and experts in the fields of education, prevention and treatment were invited to provide the Panel with evidence and support during their deliberations. Details of the Panel members are given in Annex A.

The Panel was tasked with looking at whether, and if so, how the legislative framework for responding to these new drugs could be enhanced beyond the current approach under the Misuse of Drugs Act 1971, as well as looking at how our health and education response needs to be developed. The Panel's Terms of Reference are set out below. The Panel hope that its recommendations will make a useful contribution to the Government's ongoing response to NPS.

¹ For the purposes of the Review an offline retail outlet includes high street shops (including headshops, market stalls and other non-specialist outlets such as newsagents and petrol stations). Where we have made specific reference to headshops, these are defined as a commercial retail outlet specialising in the sale or supply of NPS together with equipment, paraphernalia or literature related to the growing, production or consumption of cannabis and other drugs. These outlets may also have online businesses, but those businesses solely based online would not fit within this definition.

TERMS OF REFERENCE

The purpose of the Review is to look at how the UK's legislative response can be enhanced beyond the Misuse of Drugs Act 1971 to ensure that law enforcement agencies have the best available powers, sending out the clearest possible message that the trade in these substances is reckless and that these substances can be dangerous to health, even fatal. The Review will build on the work of the Home Office International Comparators Study which is being progressed in parallel.

The review Panel have been asked to:

- analyse the problem we are seeking to address and consider:
 - the nature of the New Psychoactive Substances market;
 - the effectiveness and issues of the UK's current legislative and operational response;
- identify legislative options for enhancing this approach;
- consider the opportunities and risks of each of these approaches, informed by international and other evidence; and
- make a clear recommendation for an effective and sustainable UK-wide legislative response to New Psychoactive Substances.

In addition, the Panel was asked to consider the education, prevention and treatment response to NPS and make recommendations.

2. Definition

For the purpose of its deliberations, the Panel adopted the definition of NPS as follows:

'Psychoactive drugs, newly available in the UK, which are not prohibited by the United Nations Drug Conventions but which may pose a public health threat comparable to that posed by substances listed in these conventions.'

The key features are that NPS are psychoactive i.e. ones that stimulate, or depress the central nervous system, or cause a state of dependence; have a comparable level of potential harm to internationally controlled drugs; and are newly available, rather than newly invented.

Under this definition the Panel considered the totality of the evidence base on NPS (whether or not they were controlled under the Misuse of Drugs Act 1971) – including the prevalence of use, availability, and the health and social harms associated with them – and looked at the range of responses on intervention and treatment, education and prevention and identification, data gathering and monitoring of harms.

A large number of NPS have already been controlled under the Misuse of Drugs Act 1971. Under its terms of reference, the Panel considered whether, and if so, how the legislative framework could be enhanced to control or otherwise regulate the availability of current and future non-controlled NPS.

3. Guiding Principles

The Panel used the following guiding principles to inform its assessment and recommendations. The Panel agreed that an effective approach to tackling NPS would:

- Align with the Government's 2010 Drug Strategy '*Reducing demand, restricting supply, building recovery: supporting people to live a drug-free life*' which balances three key themes – reducing the demand for drugs; restricting the supply of drugs; and supporting individuals to recover from dependence. This includes, but is not limited to, legislation.
- Reduce harms through early warning, prevention, early intervention, treatment and knowledge sharing, clear communications and legislation.
- Protect individuals from the risks posed by untested, unknown and potentially harmful substances.
- Provide a proportionate response supported by the evidence base which also minimises unintended negative consequences including legitimate development of medicines and other products.
- Tackle the NPS market by:
 - responding to the ease of availability which portrays the message that drug use is acceptable and can undermine public confidence:
 - in an everyday high street or retail environment;
 - internet sites advertising and sale;
 - maximising opportunities for compliance by the NPS retail market;
 - increasing the risk and lowering the reward in the market;
 - increasing successful outcomes of enforcement and prosecution actions; and
 - limiting the involvement of organised crime and the interaction with the illicit drugs market.
- Maintain/develop an effective and dynamic drug control mechanism by:
 - utilising the existing framework for controlling harmful drugs informed by advice from the ACMD through individual drug listings, broad (generic) definitions for families of NPS and, where required, rapid (temporary class drug order bans) responses;
 - removing the risk that the legislative response drives the evolution of the NPS market, particularly to more potent substances and reduces the pressures on the advisory and control processes under the Misuse of Drugs Act 1971;
 - minimising the risk of successful legal challenge; and
 - minimising overall costs and complexity to enforcement agencies and others.
- Develop the evidence base, especially where knowledge gaps need to be addressed to inform future policy responses, develop technical capability (for example, forensic science) and improve the approach to information sharing.

4. Ways of working

The Panel was established in January 2014, with its first meeting in February. It met a total of six times on a monthly basis. Its meetings and work were facilitated by the Drugs and Alcohol Unit, supported by officials from the Home Office Crime and Policing Analysis Unit, Department of Health and Public Health England.

The Panel considered nationally and internationally available evidence through a literature review and expert witness presentations. These included presentations from Ireland, the USA and New Zealand on the legislative approaches they had taken to NPS. Written submissions for the Panel were received from government departments, devolved administrations and parliamentary and non-parliamentary groups. The Panel was also represented at a 'Summit on NPS and Enforcement' held by the Scottish Government. The Panel's consideration of how the current approach to NPS should be enhanced in the areas of intervention and treatment, information sharing and prevention and education was managed through the appointment of subgroups, chaired respectively by Panel members Dr Owen Bowden Jones, Harry Shapiro and Andrew Brown. The Chairs invited experts from their wider networks to join each of the subgroups, including representatives from charities and academia. A full list of all attendees is given at Annex A.

Chapter 2: The nature and challenge of New Psychoactive Substances

The New Psychoactive Substances (NPS) area is a complex and fast-moving one which presents challenges in fully capturing the scale and the size of the issue. Despite this, there are a number of sources that provide an indication of the extent of the NPS market, although the evidence is largely based on controlled NPS, specifically mephedrone. The Panel complemented the evidence with information from members' professional experiences and their networks.

1. 'Global picture'

NPS are a global issue. The fast-paced nature of the market, increases in availability, reports of increased and emerging use in some countries and the widespread trade in these substances is drawing international concern. The United Nations Office on Drugs and Crime (UNODC) indicates that there is a worldwide spread of NPS, with 70 countries from all regions reporting the emergence of NPS in their drugs market.

The market is very dynamic with little known regarding the scale and links to organised crime. The ease of synthesis of NPS means that there are an increasing number of newer substances available. Knowledge and intelligence gaps about the trade in NPS are significant. The internet has provided a global marketplace and the emergence and sophistication of the darkweb² is concerning and gives a further platform for the growth of the market.

The global nature of the NPS phenomenon also presents opportunities for enhanced international collaboration, and the importance of data sharing within the European and international context was noted by the Panel. The UK is currently an active participant in the European Early Warning System on NPS and this network has proved useful in the early identification of emerging threats in this area. Sustained collaboration in the future would not only continue to allow the rapid exchange of information between countries but also the potential for mutual benefit through collaboration in research initiatives or through the sharing of reference material and related chemical and toxicological information.

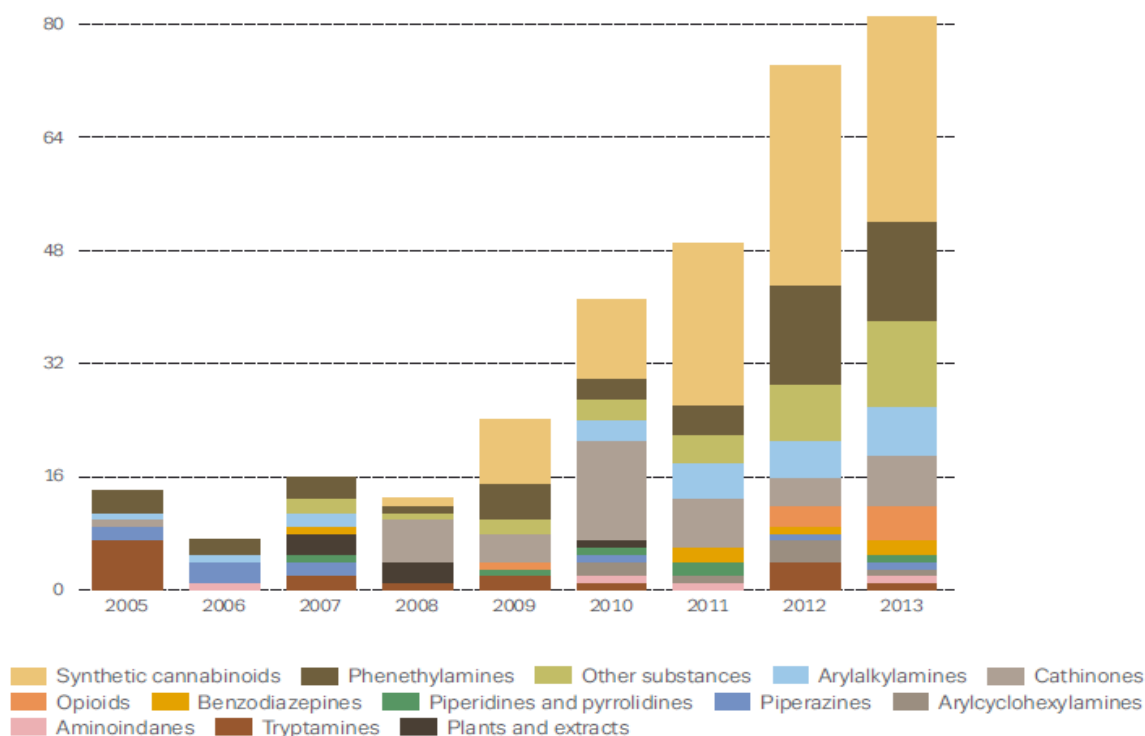
2. What we know about the problem we are tackling

a. Identification and availability

We generally have a good understanding of newly emerging NPS with effective identification systems in place at a national, European and international level. These systems show that the rate at which NPS are detected for the first time at an international and European level has increased over recent years, with a more fluctuating trend seen in the UK.

The Early Warning System (EWS) run by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) detected 81 novel NPS in 2013, an increase from 74 in 2012, 49 in 2011 and 41 in 2010. The largest group of drugs detected by the EWS are synthetic cannabinoids; a total of 102 have been detected by the EWS between 2005 and 2013, of which 29 were detected in 2013 (EMCDDA-Europol, 2014; EMCDDA, 2014a).

² The 'darkweb' refers to websites that are not openly available on the internet, and require specific software to access.

Figure 1: Number of new psychoactive substances notified for the first time to the Early Warning System since May 2005, Europe

Globally there is a similar situation; by 2013, 348 NPS had been reported by member states to the United Nations Office for Drugs and Crime (2014), up from 166 in 2009.

Overall, the UK reported 11 substances for the first time to the EMCDDA in 2013, down from 13 in 2012, the same as 2011, and lower than the 16 reported in 2010. Of the 11, 2 were first identified³ by the Home Office's Forensic Early Warning (FEWS) which was set up to quickly and effectively identify NPS. In total, since it was established in 2011, FEWS has identified 31 novel NPS, of which 10 were synthetic cannabinoids, 4 were tryptamines, 3 were cathinones, 3 were phenethylamines, and 11 were other types of NPS (Home Office, 2014a).

Analysis of NPS samples collected by FEWS found that around nine out of ten were mixtures of either two (61%) or three (30%) different active components. The analysis also found that few samples collected from the internet or headshops contained controlled drugs and, although the data is not directly comparable as FEWS collection plans differ each year, the data suggests a change over time. In 2013/14, 3.0% of internet and 4.3% of headshop samples contained controlled NPS, compared to 16.1% of internet and 63.5% of headshop test purchasing samples in 2012/13.⁴ However, 88.1% of festival samples contained controlled drugs in 2013/14, a similar level to 2012/13 (83.8%) (Home Office, 2014a).

Whilst generally there has been an increase in the number of novel NPS detected, it is important to note that the vast majority are permutations of groups of similar substances with similar effects (e.g. cathinones), or dissimilar substances that produce similar effects (e.g. synthetic cannabinoids), rather than new distinct types of drugs. Furthermore, it is likely that many of the

³ The remainder were identified by other forensic service providers, law enforcement casework, and other organisations. Substances detected first by other organisations may have also been identified by FEWS at a later date.

⁴ FEWS collection plans vary on a year-to-year basis and may target different aspects of the NPS market, therefore each year's figures are not directly comparable.

substances identified are not in widespread or even limited use. It may be that the market, to some extent, regulates itself with less effective or more harmful NPS only being seen for very short periods of time or in a limited number of countries. For example, of the 81 NPS reported to the EMCDDA's EWS for the first time in 2013, around half (42) had only been detected in one member state.

In terms of availability, users primarily obtain NPS from three main sources: online retailers, high-street retailers and non-retail vendors such as friends, family and street-level dealers (Smith and Garlich, 2013).

NPS are readily available online, but it does not appear that the majority of users directly purchase them from this source. The Crime Survey for England and Wales (CSEW) found that in 2013/14, 1% of regular illicit drug users reported that they sourced drugs over the internet (Home Office, 2014b). Although the exact figure is uncertain, internet purchases appear to be higher for NPS; for example, a Eurobarometer poll of 500 young people (aged 15–24) in the UK found that in 2014, 6% of NPS users purchased NPS online⁵ (European Commission, 2014). The most common source of both traditional drugs and NPS is from friends, though it is unclear the role the internet plays in the social supply of NPS i.e. the extent to which friends who supply NPS to other friends obtain them from the internet.

The EMCDDA report that in 2013 there were 651 online shops selling NPS and shipping to at least one EU member state, more than three times as many as 2010 (170 shops). In 2011, of the 651 online shops identified, 121 of these were likely to be based in the UK (country breakdowns are not available for 2012 or 2013) (EMCDDA, 2014b; EMCDDA, 2011).

There are no precise estimates of the number of offline retail outlets in the UK selling NPS. However, in 2013, the Angelus Foundation attempted to estimate the number of headshops by searching the internet and gathering information from trading standard offices. On this basis they estimated that there were over 250 headshops selling non-controlled NPS in the UK⁶ (PRNewswire, 2013). There are also recent reports of diversification in the NPS retail market, with NPS being sold from non-specialist outlets such as newsagents and petrol stations (DrugScope, 2014).

In addition to published evidence on NPS, the Panel heard reports from a number of sources on the NPS market, summarised below.

NPS are generally supplied from China and, to a far lesser extent, India, in bulk and then either repackaged and redistributed once they enter the EU or delivered directly to the UK. Wholesale web shops tend to offer named chemicals either 'off the shelf' or synthesised to order. The bulk importation of NPS is often done via mail and fast parcel services, and materials are then distributed further by retailers (online or offline), contacts or friends. New materials appear rapidly and if popular can quickly gain a foothold in the market, as was the case with mephedrone.

NPS are also available for sale on the 'clearnet'⁷ and on the 'darkweb'; generally the 'clearnet' deals with non-controlled NPS and the 'darkweb' controlled NPS. The National Crime Agency estimates there to be between 100 and 150 UK-based websites on the 'clearnet' claiming to sell

⁵ Other studies also show online purchasing at similar levels, with the exact figure varying between studies, with generally around one in ten NPS users purchasing online. For example Dargan *et al.* (2010) reported 10.7%, and a previous Eurobarometer reported 7.2% (European Commission, 2011).

⁶ The number does not include market stalls or under-the-counter sales.

⁷ The 'clearnet' refers to websites that are openly available on the internet.

non-controlled NPS – this figure varies on a weekly basis. The ‘quality’ of websites appears to differ widely with some reliably delivering orders and offering a complete ‘customer experience’, using offers and vouchers to promote products and providing a rating opportunity, whilst others are ‘ghost sites’ which advertise goods and take money, but have no intention of delivering a product. A number of NPS websites are owned and operated by the same individuals and a number of site owners use ‘contact privacy’ services to hide their identity. Sellers do not always advertise all their products openly on their internet site and sometimes offer a more extensive list once they build a ‘rapport’ with customers. Payment methods include bank transfers, E-money and virtual currencies.

There seems to be a move by suppliers selling non-controlled NPS on the ‘clearnet’ to stay within the margins of current drug control legislation, with considerably fewer NPS products on open sale being found to contain controlled substances than was the case in 2011, a view supported by intelligence from the National Crime Agency and the latest data from the Forensic Early Warning System (see p.7). Forensic analysis has found substances available online that are misdescribed or with brand names giving no information on contents; however, when stated, chemical names of active ingredients do now tend to reflect the contents of products. To avoid consumer protection and similar legislation, as described in Annex C, ‘clearnet’ suppliers are usually careful to avoid any indication that their products are intended for human consumption, so dosage advice is offered in oblique wording, if at all.

‘Darkweb’ sites such as ‘Silk Road 2.0’ operating through The Onion Router (TOR) sell illegal drugs of all types, including controlled NPS. The anonymity provided is likely to encourage the sale of illicit substances – ‘darkweb’ sites tend to give more in-depth instructions to users on dosages and how to take certain NPS.

b. Prevalence of use of New Psychoactive Substances

We do not have a complete picture of the overall prevalence of NPS use; however, the available evidence suggests that use of NPS is generally low compared to the more frequently used illicit drugs such as cannabis, powder cocaine and ecstasy, although use is higher in certain subgroups.

The most robust data on drug use at the general household population level comes from the Crime Survey for England and Wales (CSEW). The Crime Survey, whilst not capturing the full range of NPS, has added questions on selected NPS over recent years (Table 1). Mephedrone is the most prevalent of the NPS, though use has fallen from 1.3% in 2010/11 to 0.6% in 2013/14 (Home Office, 2014b). The use of other NPS measured in the Crime Survey has remained stable or fallen. At its peak, prior to control, mephedrone was the ‘market leader’ in NPS and has not been replaced by a similarly popular NPS. It is likely that mephedrone use has fallen due to a number of factors such as control, a growing awareness of harms and increased purity and availability of drugs such as ecstasy.

Table 1: Proportion of 16- to 59-year-olds reporting last year use of NPS, 2009/10 to 2013/14, England and Wales, percentages

	2009/10	2010/11	2011/12	2012/13	2013/14
Mephedrone	N/A	1.3	1.0	0.5	0.6
Salvia	N/A	N/A	N/A	0.3	0.5
GBL/GHB	0.1	0.0	0.1	N/A	N/A
Spice	0.4	0.2	0.1	N/A	N/A
BZP	0.5	0.1	0.1	N/A	N/A

Similarly to most other drug types, use of NPS is higher among young adults. However, the overall decrease in mephedrone use remains. Last year, use of mephedrone among 16- to 24-year-olds fell from a peak of 4.4% in 2010/11 to 1.9% in 2013/14.

A question on mephedrone use was added to The School Survey of Smoking, Drinking and Drug Use in 2012. The latest results from 2013 show that 0.4% of pupils reported that they had taken mephedrone in the last year, a similar level to 2012 (0.7%) (Fuller and Hawkins, 2014). For comparison, in 2013, 7.0% of pupils reported taking cannabis in the last year, and 3.6% of pupils reported taking volatile substances (glues, gases, aerosols and solvents).

We have a relatively in-depth understanding of NPS use in specific subgroups, particularly nightclub-goers, though methodological limitations mean results cannot be generalised. For example, The Global Drug Survey (GDS), a self-selecting online survey initially aimed at readers of the dance music/clubbing magazine *Mixmag* (other media partners are now included), found that 12.5% of regular clubbers⁸ reported using mephedrone in the last year (Mixmag, 2014). Although sample changes mean that the findings are not directly comparable, 51% of regular clubbers reported mephedrone use in the 2010 Mixmag survey (Winstock, 2011).

Against this general downward trend in mephedrone use since 2010 in both the general population (CSEW) and among clubbers (GDS) are subgroups with continued high levels of use, including gay/men who have sex with men clubbers. Annual surveys in gay-friendly nightclubs in South London have found continued high prevalence of use and popularity in 2010–14 (for example, Measham *et al.*, 2011a; Wood *et al.*, 2012a) due to low price, easy availability and enhancement of sexual activities.

There are limitations to survey data which are likely to result in the underreporting of NPS use (and to some extent traditional illicit drugs). For example, due to the fast moving nature of the market, surveys are not able to measure all NPS and they are only usually added once they have become established, limiting the ability to monitor trends over time. For example, mephedrone was added to the 2010/11 Crime Survey, over a year after use had become popular. Additionally, for all self-report surveys, there are likely to be issues of validity, as users may not be able to accurately identify which substances they have taken; this is exacerbated by the mislabelling of many NPS products.

c. Harms

There is a general lack of comprehensive evidence on the toxicity, abuse liability and risks associated with long-term use of NPS. Additionally, there is likely to be underreporting of health harms due to the lack of recording mechanisms for NPS-specific harms and many professionals in the health, treatment and prevention fields lacking awareness of the range of NPS in use. This is compounded by the fast pace of development of NPS, which makes it difficult to stay informed of all the available substances. Evidence on social harms associated with NPS use is even more limited.

Information provided by EMCDDA states that if considered individually, as single substances, most NPS, in terms of what is known about their prevalence or health consequences, would not appear to be particularly important at the population level even if some are clearly damaging to individuals. However, considered as a group, the European data available would suggest that in terms of both prevalence and health-related problems, NPS now constitute an important component of the overall drug problem.

⁸ GDS defines regular clubbers as respondents who have been clubbing in the last month.

Health harms

The UK has nationally collected data on NPS-related deaths and numbers in treatment but less is known about long-term health harms of NPS use or acute toxicity which does not result in death.

National statistics on deaths related to drug poisoning show that deaths related to NPS in England and Wales increased from 29 deaths in 2011 to 52 deaths in 2012. The majority of NPS-related deaths in 2012 were from cathinones (18 deaths) and GHB/GBL (13 deaths) (ONS, 2013). However, it is not possible to ascertain from the data whether a death was directly attributable to a specific substance, as many drug-related deaths involve multiple substances and alcohol.

The Panel also suggested that a number of NPS may be missed in toxicological analysis, particularly as some NPS are effective at very low doses. Further, when such compounds are found, the lack of data on the effect of these NPS means that toxicologists may be reticent about making definite statements about the role the NPS played in the death.

Similarly, the number of clients entering treatment in England reporting mephedrone use has increased from 839 in 2010/11 to 1,630 in 2012/13. A similar picture can be seen in under-18s. In 2010/11, 972 under-18s entered treatment reporting mephedrone use; this then increased to 1,788 in 2012/13 (Public Health England, 2013a; Public Health England, 2013c).

To put this in context, NPS deaths and treatment presentations are low when considered against the 1,496 drug-related deaths (most of which are opioid-related) and 69,247 new presentations to treatment across the same time periods.

The National Poisons Information Service (NPIS), which provides advice on poisonings to NHS clinicians, reports that poison centre contacts⁹ for mephedrone have been declining since April 2010, but remain higher than other NPS. 'Legal highs' (substance not specified) and mephedrone were in the top ten for telephone enquiries. Other NPS enquired about included alpha-methyltryptamine (AMT) (13th), synthetic cannabinoids (15th), 5/6-APB (16th) and 25I-NBOMe (22nd) (Public Health England, 2013b).

Social harms

There is very little evidence on a link between social harms and the use of NPS. It is plausible to assume that the social harms of NPS use have the potential to be comparable to the drugs they mimic – largely ecstasy, amphetamine, cocaine, cannabis and ketamine. At present, the vast majority of NPS are not imitating heroin and crack cocaine, which have the strongest link to drug-related crime (particularly acquisitive crime) and other social harms. However, opioid NPS have now started to emerge and this may potentially lead to increases in social harms.

There have been reports of concern about NPS at a local level and instances of local media interest. Several MPs have raised the issues of anti-social behaviour around headshops and headshop sales to under-18s in Parliament (Hansard, 2014). Although these reports do not provide a systematic estimate of the overall scale of these problems at a national level, they clearly reflect the local concern about potential social harms of NPS.

⁹ Poison centre contacts are not a direct measure of patient presentations or toxicity, but do give a good indication of the substances encountered by NHS physicians.

d. Motivations for use

Whilst we do not have a comprehensive understanding of the motivations for using NPS, it is likely that for the majority of users the motivations are similar to those for taking illicit drugs. However, for some specific subgroups, there are distinct attractions to NPS as opposed to controlled drugs.

It is likely that price, purity, availability, effects and legality play a part and that by understanding the relationship between these different motivations (and crucially also their relationship to illegal drugs) we can identify several key groups of NPS users (Measham, 2013, 2015).

NPS use is likely to be initiated for reasons such as curiosity, boredom, peer pressure and loneliness; once use has been initiated, it is likely that users continue to use as they enjoy the effect. These reasons are similar to those given for initiating use of traditional illicit drugs (Fuller, 2012).

For the most part, NPS use seems to be confined to existing drug users and therefore the legal status of NPS may not be the main factor driving use for many users (with the exceptions discussed below). The CSEW found that in 2013/14, 98% of those who reported mephedrone use in the last year had also used another illicit drug over the same time period (CSEW, 2013/14).

The Panel heard evidence from Professor Measham that NPS are often more popular when the purity and availability are low for established illegal drugs such as MDMA and cocaine, as was the case in the UK in 2008/09. By contrast, there was less interest in the second generation NPS that appeared immediately after synthetic cathinones were controlled in 2010 (Wood *et al.*, 2012a).

Mephedrone in particular has established itself as a popular drug among London gay/men who have sex with men clubbers in the four years since legislative control, often taken alongside other controlled drugs such as ketamine and GBL (Measham *et al.*, 2011a; Wood *et al.*, 2012b). For men who have sex with men clubbers, NPS seem to be taken to supplement, rather than displace, established illicit drugs (Moore *et al.*, 2013), whereas mephedrone use remains relatively low among non-men who have sex with men clubbers and outside of London.

There appear to be other groups such as prisoners, professionals, military personnel and younger users for whom the legality of non-controlled NPS is an important consideration, and for them use may be driven by the wish to avoid detection or criminal sanction. Regarding younger users, NPS may have an appeal for under-18s who cannot readily access either established illegal drugs (if limited access to street dealers, particularly in rural and suburban areas) or alcohol (given that the minimum purchase age for alcohol of 18 is increasingly strictly enforced through 'Challenge 21' and 'Challenge 25' schemes at licensed premises). Offline retail outlets may be more popular than online retailers for people under 18 to purchase NPS due to the ability to make cash purchases for those who may not have access to non-cash payment facilities such as debit cards; also for professionals who do not want their purchases to be traceable.

These various motivations result in several key groups of NPS users along with the (i) cyber-psychonauts,¹⁰ including (ii) gay/men who have sex with men drug users as part of their wider polydrug repertoires, (iii) teenagers under 18, (iv) professionals and (v) prisoners/those in touch with criminal justice agencies who wish to evade detection and drug tests.

¹⁰ Psychonaut is used to refer to those who experiment with psychoactive drugs often with the aim of expanding the limits of human thought and consciousness. These users often take detailed notes, take part in online discussions and have excellent technical knowledge (Davey *et al.*, 2012).

Furthermore, there are differences in the cultural value attached to NPS among different groups of young adult drug users. For example, there is evidence that some users are unconcerned about the content of the substances they are taking, purchasing stimulant white powders containing variable mixtures of cathinones, sold as 'Bubble' in the north-west of England (Measham *et al.*, 2011b). By contrast, research in contemporary dance clubs (Measham, 2015) suggests that MDMA remains popular in pill, powder and crystal form and that NPS are considered 'cheap and tacky' among some experienced clubbers.

e. Motivations of suppliers and distributors

The Panel heard that there is a wide range of suppliers operating across the spectrum in terms of legal and illegal activity; these suppliers may have different motivations and operate to different standards.

The Panel sought an insight into the NPS business and the motivations of NPS retailers from Professor Measham, who is conducting ongoing research with some of the key UK NPS retailers (Measham, 2015). The Panel were mindful of the fact that the interviewees volunteered to take part and therefore may be more likely to represent the more responsible side of the industry. Additionally, even if retailers are acting responsibly and within the law, NPS may still be dangerous products to trade in. It was acknowledged that the participants could not be considered to be representative of all NPS suppliers and distributors.

Case study: Responsible retail practices – perspectives from NPS retailers (online, wholesale and 'headshop' owners)

Those spoken to indicated that they had entered the 'NPS business' in around 2008/2009 when mephedrone entered the market and now have multi-million pound businesses. They reported that they had no desire to break the law and described how they went to considerable efforts to keep within the law. For example, the retailers regularly monitored government and other websites to keep up to date with legislative changes. If a substance was controlled under the Misuse of Drugs Act 1971, it was removed from sale and an alternative product developed and sold. They utilised independent chemical analysis to confirm the content of their products and avoid mis-selling controlled drugs. None was involved in the sale of controlled drugs, either online or offline.

These retailers felt that temporary bans could be effective for dangerous substances and indeed proactively removed some products from sale if they were concerned about their safety record, for example if they heard negative safety reports from overseas and they felt the UK Government was slow to take action. However, they noted a problem with temporary class drug orders (TCDOs) regarding how to safely dispose of old stock when an NPS was banned; a short time period encouraged deep discounting and 'fire sales' of soon-to-be banned stock. Therefore they advocated a more realistic amnesty period to facilitate more responsible disposal of discontinued stock.

They addressed two inaccuracies in press coverage of NPS retailers – the age of their customers and the sale of controlled substances as legal NPS. The headshop owner described some benefits from face-to-face sales as opposed to online sales including the opportunity to ID customers for proof of age, as well as refusing to serve apparently intoxicated customers. The online retailers also made efforts to check that customers were over 18, although more limited due to the nature of online business. Both online and offline NPS retailers reported that their customer base included professional people in jobs which involve workplace drug testing, for whom the appeal of NPS may be to evade such screening tests or simply to avoid the risk of

prosecution. In general, the retailers saw their customers as motivated by the reliable content and purity of legal NPS by comparison with illegal drugs, as well as avoiding the risks related to possession of controlled substances and interactions with street dealers.

Whilst unscrupulous NPS suppliers had got rid of banned NPS stock when controlled in 2010, the retailers claimed that most NPS retailers now test and sell accurately labelled NPS that are not controlled under the Misuse of Drugs Act 1971.¹¹ All retailers reported that they felt a duty of care towards customers and would like to provide more safety information to consumers but were restricted by 'regulations'. A particular concern related to being unable to provide information on accurate dosage given that the active dose for some NPS is very low, knowledge of NPS potency is limited, and yet NPS products can be bought in unrestricted quantities.

The NPS retailers were in the process of developing a code of practice in the UK to establish guidelines on social responsibility in the NPS trade similar to that in the alcohol industry. They were keen to emphasise their own responsible retail practices and distance themselves from both organised criminals and from less scrupulous NPS retailers – who they suggested included garages, corner shops and newsagents – selling NPS as a sideline to their main business.

Professor Measham, 2014

The Panel also heard from enforcement colleagues who provided a view of suppliers not operating within the law.

Case study: NPS week of action (November 2013)

The police, the National Crime Agency, Border Force, Her Majesty's Prisons and trading standards took part in a week of enforcement activity targeting the sale of controlled NPS. This action was based on police intelligence suggesting that controlled NPS, such as the Class B drug mephedrone, were being traded on the open web on 'legal high' websites.

The results of this activity suggest links between elements of the NPS market, the sale of controlled substances and wider criminality. For instance, the National Crime Agency arrested NPS suppliers in Huddersfield and Oldham, seizing half a kilogram of controlled NPS. Officers from the Metropolitan Police recovered a firearm at one address, and a drugs factory was found in Hampshire. In total, 73 warrants were executed as part of this activity, leading to 44 arrests.

Panel members raised concerns that those attempting to work within the boundaries of the law may still be acting irresponsibly, given the potential harms of the substances being sold and the lack of product testing.

f. Interaction with the supply of illicit drugs

The extent to which organised crime or other criminal supply routes are involved in NPS distribution and sales is uncertain, although there have been reports of organised crime involvement in mephedrone supply since it was controlled in 2010 and the illegal market developed.

¹¹ NCA intelligence supports the view that considerably fewer NPS products on the 'clearnet' are currently being found to contain controlled substances than was the case in 2011, and recent FEWS data found that only a small proportion of samples collected from headshops and the internet contained controlled substances.

Whilst data on mephedrone seizures is patchy, the Home Office stated that a 54% increase in Class B drug seizures between 2011/12 and 2013/14 is largely due to mephedrone and other cathinone derivatives becoming controlled, particularly for police seizures (Coleman, 2013). The price of mephedrone appears to have increased since it was controlled. The annual Focal Point report of the drug situation in the UK cites data from law enforcement agencies which shows that the street price increased from £10.00 per gram in 2010 to £20.00 per gram in 2012 (Davies and Murray, 2013).

Some NPS are currently supplied by organised crime groups (OCGs), either being used to adulterate controlled drugs or passed off as controlled substances. For example, the EMCDDA (2014c) report that 4-MA was predominantly supplied by the same OCGs that supplied amphetamine, and Europol has also recently reported some evidence of limited NPS production in Europe by groups involved in illicit synthetic drug production. Concern about possible growing interest of OCGs in the NPS area is also prompted by the observation of seizures of NPS which have been mixed with the same cutting agents that are typically found with drugs like cocaine or amphetamine. The available evidence only suggests limited OCG activity in the NPS area, however, as these substances become controlled, and in the context of the dynamic nature of the drug market, this could change rapidly and therefore vigilance on this issue is called for.

Conclusion

We are beginning to get a better picture of the NPS market but still have significant evidence gaps around prevalence, purchasing and supply. Furthermore, we have a very incomplete understanding of acute and longer-term health harms and we know very little about any associated social harm. There is little evidence of NPS use driving crime and disorder, though organised crime groups are likely to become involved in supply if deemed profitable, as was seen in the case of mephedrone post-control. At present, NPS appear to be less used and associated with less harm than traditional illicit drugs, particularly opiates and crack cocaine. However, all available indicators suggest that the harms from traditional illicit drugs are largely declining while the harms from NPS are increasing.¹² This, together with sizeable evidence gaps about the impact of use and the rapid pace of development, means that NPS remains an area of concern and interest.

¹² This conclusion was based on the evidence available to the Panel in July 2014 when it finalised its report.

Chapter 3: The UK's response to date, the effectiveness and issues of the UK's current legislative and operational response and ongoing challenges

The Panel received information about the UK Government's response to-date covering identification and data collection, implementing legislative responses, raising public awareness, promoting international co-ordination and treatment. This response had been directed by the Government's 2012 NPS Action Plan, which had been informed by the ACMD's Report "Consideration of the Novel Psychoactive Substances ('Legal Highs')".

- **Early detection:** In 2011, the Home Office established the Forensic Early Warning System (FEWS) to understand what NPS are available in the UK, to support law enforcement and to provide forensic laboratories with the chemical reference standards they require to identify any novel NPS.¹³
- **Data collection:** The Drugs Early Warning System (DEWS) was established in 2012 to collect data on harms at a regional, national and international level. To date, the system has been used to request data on specific drugs for the purpose of informing the ACMD's consideration on advice for control, whether temporary or permanent control, under the Misuse of Drugs Act 1971.
- **Legislation:** The existing legislative framework under the Misuse of Drugs Act 1971 has been used extensively by deploying both broad and rapid mechanisms for banning substances. The UK also works within the overall EU legislative framework established in 2005¹⁴ to respond to NPS.
 - Following statutory consultation with the ACMD, the UK has listed individual NPS as well as used 'generic' or group control, whereby families of drugs have been controlled. To some degree, this has 'future proofed' against future modifications. Over 550 NPS have been controlled since 2009, with 350 controlled since July 2010.¹⁵
 - Temporary class drug orders (TCDOs)¹⁶ were introduced in 2011 to supplement existing drug controls where there is a pressing need to legislate fast, i.e. in a matter of weeks not months after receiving expert advice. To date, two such orders covering 15 NPS have been made. All 15 NPS have subsequently gone on to be permanently controlled.

The UK has banned the majority of NPS seen in the EU since 2005. Of the 410 NPS identified in Europe up to 2014¹⁷ (EMCDDA-Europol, 2014), over 85% of the main groups are already controlled, and of the 73 NPS reported in the EU in 2012, only 23 have been seen in the UK (14 already controlled).

A range of alternative legislation, including consumer protection and similar legislation, was used in the UK to tackle non-controlled NPS (see Annex C¹⁸). Whilst these were not robust

¹³ Novel NPS referred to here are NPS that have not previously been detected.

¹⁴ Council Decision 2005/387/JHA.

¹⁵ It is important to note that this number covers eight groups of NPS drugs covering three drug type classes – synthetic cannabinoids, stimulants and hallucinogens; that it includes NPS seen in the EU as well as the UK and it covers their likely variations that have yet to be seen.

¹⁶ All the offences that apply to a controlled drug apply to a TCDO, except the offence of simple possession.

¹⁷ As at June 2014.

¹⁸ The recent judgment of the European Court of Justice (Joined Cases C-358/13 and C-181/14 - D and G) is consistent with the UK's use of medicine legislation to tackle NPS, namely that 'medicinal products' can only be used to refer to products which have a clear therapeutic benefit, as opposed to those that are consumed solely to induce a state of intoxication.

models for NPS, there were emerging opportunities with their use, and a number of areas in the UK are trying to find innovative ways to address the sale of non-controlled NPS to supplement the traditional enforcement response.

- **Demand reduction:** The Government ran a targeted communications campaign to raise awareness of the risks of taking NPS through the summer festival season in 2013. The communication was highly targeted to contemplators and dabblers¹⁹ to avoid raising awareness of NPS to those who may not otherwise be aware of them. In addition, the Government's drug awareness service, FRANK (www.talktofrank.com), continues to be updated so that young people are aware of the harms of both controlled drugs and the risks associated with non-controlled NPS. These updates reflect the advice from the ACMD and the latest available evidence.
- **International collaboration:** The UK has been active on the international scene in exploring how to tackle NPS globally. It has been sponsoring the international early warning advisory system and a platform for international exchange of data through the United Nations Office on Drugs and Crime (UNODC); at the Commission for Narcotic Drugs, it has led resolutions on the identification and reporting of NPS; used its Presidency of the G8 to coordinate approaches to source countries and has been a key participant in the debate on future international controls, and has called on other member states to provisionally control mephedrone pending the outcome of a review by the World Health Organisation.
- **Treatment:** The UK's first set of clinical guidelines for NPS, care bundles and a UK clinical network are being developed ("Project NEPTUNE (Novel Psychoactive treatment: UK network)") with the purpose of up-scaling the competence of clinicians in detection, assessment and management of NPS users.

Ongoing challenges

The Panel heard about the ongoing challenges.

- **Evidence base:** An often-underdeveloped evidence base frustrates the ability to respond in a timely manner.
- **Legislation:** The processes under the Misuse of Drugs Act 1971 to bring a drug under control are dependent on evidence of harms being available. The classification of a drug(s), as seen with NPS over the last five years, is a repetitive advisory and parliamentary process with resource implications. The apparent consequences of this approach to date appear to be an inevitable time lag between an NPS coming on to the market and a legislative response under the 1971 Act. On the other hand, the NPS market is now more responsive to legislation in a way that appears to be driving the availability, if not the development, of new NPS with the indication that the faster controls are put in place the greater the rate of new NPS coming to market and in some instances, the greater the potency of these products.

A further aspect that was raised concerned temporary class drug orders. Orders are made for a period of up to 12 months only. They require the ACMD to provide a full assessment of harms within six or so months to allow the parliamentary procedure for permanent control, if that is the decision, to be completed. Often little new evidence is available in this time and it does place extra pressures on the ACMD.

¹⁹ 'Contemplators' and 'dabblers' are those who have considered taking NPS, or taken them once or twice.

- **Enforcement:** There are challenges around detection and identification of NPS compounded by the ever-changing chemical composition of the substances, availability of up-to-date indicative testing technology and the ensuing associated forensic costs. The intelligence picture about the trade, particularly on the internet, is very limited, as are police and Border Force powers for dealing with substances not controlled under existing drugs legislation. Whilst at importation, Border Force can seize a package where there is clear evidence that the accompanying customs declaration is either incomplete or inaccurate in terms of description and/or valuation of contents, in the absence of definitive, 'real time' identification there are often no legal grounds available to support ongoing detention or seizure.

The National Crime Agency does not have many available powers if a website is not identified as selling products that contain controlled substances. The level of evidence needed to remove a website involves satisfying the domain name provider that an offence has been or would be committed. This has some difficulties if it involves a UK-registered site but can be significantly more problematic in a country without similar legislation or co-operation. The variety of e-currencies makes disrupting website sales more difficult to achieve. It can also be difficult to identify the people behind each website who may anonymise their identity.

The international legal position of individual NPS can therefore cause difficulties for enforcement agencies, particularly as different countries control NPS in different ways. The UK tends to have more extensive drug-specific controls in place, so if suppliers/retailers are based overseas, enforcement agencies need to establish the legal position of the NPS in the country it is being shipped from.

- **Prosecution:** The Misuse of Drugs Act 1971 offers a number of benefits, including legal certainty and familiarity, and the definitions used in the Act have rarely been challenged. However, NPS have added a layer of complication to bringing cases to prosecution. Due to the nature of NPS, there are greater opportunities for defendants to argue that they did not believe or suspect that they were supplying (or in possession of) a controlled drug. A statutory defence to this effect is provided by the 1971 Act. In some cases, suppliers will obtain certificates from their wholesalers to support this line of defence. In response, the police in some areas have issued letters to offline retail outlets warning them of the legal risk of selling NPS. The Panel considers that, in view of the diversity of NPS and circumstances of offences, prosecutors would benefit from the publication of specific guidance on the prosecution of offences relating to controlled NPS.
- **Use of alternative legislation:** While other legislation offers opportunities to regulate or prevent the sale of NPS, none of the options being used or contemplated is ideal as they are not designed to deal with the particular issues associated with NPS. Prosecuting authorities encounter a number of barriers that prevent their effective use. There has been a focus to date on using consumer protection legislation. This has proved problematic because the underlying objective behind consumer protection legislation is to create better regulated markets, rather than to shut down a certain sector of the market. Trading standards officers have, for example, struggled to make use of the Consumer Protection from Unfair Trading Regulations for this reason. There is wider scope under the General Product Safety Regulations (GPSRs), and some local authorities, such as Belfast City Council, have succeeded in using these regulations to seize and forfeit NPS products (see case study at Annex C). The GPSRs can be a useful tool for enforcement on some issues, such as affecting how NPS products are labelled, although it is more difficult to use them to directly tackle the issue of ongoing supply.

Other forms of legislation are also applicable in some circumstances, such as the Intoxicating Substances (Supply) Act 1985. This Act prohibits the sale to under-18s of substances which the

seller has reason to believe will be inhaled for the purpose of intoxication, and has been used to prosecute sellers of synthetic cannabinoids (see case study at Annex C). Prosecutions under alternative legislation are often costly (with costs not likely to be recovered on conviction) and, depending on the offence being charged, local authorities may need to evidence the harms of particular products, which can be problematic. It is also questionable whether the sanctions for breaching much of this legislation (such as relatively small fines or forfeiture of products) are sufficient to provide a deterrent. This position may change as the applicability of the GPSRs to the NPS market is tested in the courts, but as NPS retailers adapt to the changing legal environment (as they have already done), a point may be reached where the GPSRs are no longer a useful tool. In these circumstances, other areas of legislation such as the Local Government Act 1972 may offer scope for action, but again their use will not be straightforward. Partnership working, for instance between trading standards officers and the police, can assist in overcoming the barriers to successful prosecutions mentioned above, as expertise and resources can be shared across organisations. The alternative legislation which has been applied to NPS (detailed at Annex C) is not an appropriate mechanism for a sustainable, effective response to this issue. However, given the right circumstances it can provide tools to disrupt the supply of NPS in local areas.

The Panel was advised that to improve the impact of current consumer protection legislation consideration should be given to issuing practical guidance for enforcers with precedents for each area; training and support for Local Authority Legal Teams as well as Trading Standards Officers; and that consumer protection legislation could be ‘opened up’ and made accessible to more enforcement agencies than just trading standards.

- **Forensic science:** When a new substance enters the UK market, forensic providers are required to develop, and obtain accreditation for, a new analytical method to identify the substance to an evidential standard. This has a significant cost which is either passed on to customers or, if insufficient cases involving this substance are submitted, met by the provider. Some NPS have closely related chemical structures making them difficult to distinguish using the analytical techniques routinely employed in forensic science laboratories, so that advanced analytical techniques have to be employed. This can be a particular problem if one possible structure is controlled but another is not. If the laboratory does not have the relevant chemical reference standards (well-characterised samples of the materials of interest) to support the analysis of suspected NPS, these can be expensive to purchase. If reference standards for novel compounds are not yet commercially available, these can be costly and take time to produce.

Conclusion

The Panel considers that the Misuse of Drugs Act 1971 is a framework that is tested and well understood by the public and practitioners. The use of generic definitions maintains a very good level of coverage over NPS identified in the UK and the EU. It also maintains a strong link to the evidence base of drug harms and legal certainty.

Whilst the UK has not seen any significant market developments for a number of the NPS groups, this approach is unlikely to get fully ahead of the NPS market. It also allows the NPS suppliers to adapt their range of NPS on sale in response to new controls. Whilst it provides opportunities for sellers to comply, this approach is nonetheless allowing a profitable market for NPS to thrive in the highly visible marketplaces of the offline and online retail outlets. There are signs that some of the alternative legislation is starting to be effectively deployed; however, the powers to prosecute suppliers of non-controlled NPS remained limited and are resource and cost intensive.

The Government already has systems and interventions in place to address ongoing challenges around Information Sharing, Treatment and Intervention and Prevention and Education, for traditional illicit drugs with some more recent NPS-specific initiatives. However, it is important to fully consider whether these sufficiently meet the challenges inherent in the fast-changing and often unknown nature of NPS (see Chapter 5).

Recommendations for the existing system

Recommendation 1.1: Building on the UK's balanced approach: The Government should build on its balanced approach to date to tackle NPS that has been wide ranging and has real strength, particularly through the establishment of the Forensic Early Warning System, the use of generic definitions and work on global co-operation and demand reduction, all of which have influenced other countries' own responses.

Recommendation 1.2: Consider extending the temporary class drug order: In consultation with the ACMD, the Government should consider extending the period for which a temporary class drug order can be made, from up to 12 months to 24 months.

Recommendation 1.3: Update local authority guidance on tackling NPS: The Home Office and local government partners should update the guidance for local authorities, originally published in December 2013, to reflect the latest cases in this area and the developing legal field.

Recommendation 1.4: The Crown Prosecution Service to consider issuing specific guidance on controlled NPS: The Crown Prosecution Service should consider issuing specific guidance to assist prosecutors in addressing the issues that might arise in prosecutions for NPS.

There is a case for an enhanced legislative response as the process for controlling drugs remains inherently reactive to developments in the NPS market and, at worst, is driving its development; whilst there are developments in the use of alternative legislation, there remains an incomplete enforcement tool-kit that is required to tackle the availability of non-controlled NPS.

Chapter 4: Legislative approaches for restricting supply

Introduction

The major challenge to a legislative response to NPS is the range of new substances that have appeared on the market, the potential for more, the rate at which they appear and the ability to risk assess their health harms to inform a legislative response.

The Panel identified a range of main options for enhancing the UK's current legislative approach to better respond to these challenges, including those that had been introduced in other jurisdictions. A common impact framework was developed to test the **potential** impact and possible unintended consequences of each one against common criteria informed by national and international evidence or, in its absence, the Panel's expert opinion. As the framework captures the views of the entire panel, there will inevitably be contradictory views. The opportunities and risks are not ranked by importance or likelihood, neither are they exhaustive. Any increases or decreases are in reference to the current UK situation as a baseline.

The Panel was mindful that as these approaches have not been implemented in the UK, it is difficult to fully predict their impact, and there may be unintended consequences that have not been identified.

In some instances, factors have been identified that could be viewed as both opportunities and risks. For example, if displacement to alcohol happened as a consequence of an approach, theoretically, this could increase or decrease total harms depending on the level of alcohol consumption and the type of substance it displaced. When this is the case, these factors have been added to both the opportunities and the risks.

Key opportunities and risks are presented under each model; for a more detailed list of all opportunities and risks identified by the panel, see Annex D.

The framework covered the opportunities and risks against the following:

- the supply chain;
- demand;
- harm;
- enforcement;
- forensic science;
- legal services;
- associated costs; and
- messaging and communications.

Many countries have adopted alternative legislative approaches outside their standard legislative procedure for controlling NPS which have included the use of analogue and generic terms, temporary and emergency procedures and regulation. All of the approaches used have practical, legal and presentational opportunities and risks. Where some of the approaches have been adopted in other countries, the evidence of impact is not fully developed, nor have detailed monitoring procedures been put in place to assess the effectiveness of the legislation.

The Panel was also mindful that the drugs market and underlying challenges were different between countries, with each country having its own legislative approach which may limit or influence the opportunities and risks of implementing the models in the UK. Some countries also have in place a national forensic science service capability. In the UK we do not have an overarching national forensic science service, which presents challenges in responding to aspects of the additional forensic science activities required by some of the models reviewed.

The Panel has logged the key *potential* opportunities and risks of each model as part of this report and it is for the Government to consider how it will mitigate against these when considering how to implement any recommendations.

Extension of existing laws and/or adopting different process

A. ANALOGUE APPROACH

Principle

An analogue system controls substances even though they are not specifically mentioned in legislation by invoking the concept of ‘chemical similarity’ to a drug already controlled.

Countries that use analogue legislation have all taken different approaches to how it is written, applied, interpreted and the penalties associated with it. Some countries supplement the analogue clause with an additional requirement of pharmacological activity or require additional proof that the substance has been sold for human consumption. Details of different countries’ approaches to analogue legislation are provided in Table 2.

Table 2: Details of the different analogue approaches in the different jurisdictions

Country	Chemical Similarity	Pharmacological Similarity	Sold for Human Consumption	Covers analogues of all drugs in the legislation
United States	✓	✓	✓	✓ ²⁰
Australia	✓	X	X	✓
New Zealand	✓	X	X	X
Canada	✓	X	X	X
Latvia	✓	✓	X	✓
Norway	✓	✓	X	✓

Case study: The US Analogue Act

The Expert Panel heard evidence on the United States (US) Analogue Act from both the US Drugs Enforcement Agency and Department of Justice.

The US Congress enacted the Controlled Substance Analogue Enforcement Act of 1986, as a mechanism to respond to ‘underground chemists’ who were producing designer drugs for human consumption that were not specifically named under existing legislation. Generally, if a person traffics in a substance that meets the definition of a ‘controlled substance analogue’ (see Table 1) they could face prosecution under US Federal Law. (In addition, several states, notably including Michigan, have had success using their respective state controlled substance analogue laws.) Taking together the definitional and operative sections of the Controlled Substances Act, to convict a person of trafficking a ‘controlled substance analogue’, the following elements of proof are necessary under Federal law: (1) that the chemical structure is substantially similar to the chemical structure of a controlled substance in schedule I or II, and either (2) that the stimulant, depressant, or hallucinogenic effect on the central nervous system (CNS) is substantially similar to or greater than that of a controlled substance in schedule I or II, or instead of the second element; or (3) the government may prove that in a particular case, the defendant *intended or represented* that the substance has a similar or greater effect on the CNS as a schedule I or II controlled substance. An additional element of proof is that the substance was intended for human consumption (and not the cleaning product, bath salt, or other product

²⁰ Only schedules 1 and 2.

sometimes appearing on the label to evade apprehension).

From the beginning of January 2011 to present, there have been in excess of 130 indictments charging over 430 defendants in the US involving analogues. Over 185 of these cases have been resolved through plea bargains entered into by defendants after the prosecution presented to the defence the evidence in the case.²¹ Where cases have been contested in court, the prosecution has so far been successful. This is due to the extensive investigations undertaken by law enforcement, most often through the Drug Enforcement Administration (DEA) and the high quality of the expert evidence provided by prosecution witnesses.

Like all US criminal drugs cases, investigations can include covert purchases and seizures, court authorised warrants and extensive forensic lab analysis. A well-planned investigation would also seek to elicit the suspect's understanding of the nature of the substance being trafficked. This is important in light of a difficult issue, resolved in different ways among the several circuit courts of appeals, involving what (if anything) a defendant must know about the structural characteristics and pharmacological effects of the substance at issue.

These cases are generally very resource intensive for law enforcement and prosecuting authorities. The facts of the case are presented to the jury, which often must assess differing expert testimony by scientists, and may include actual user experiences. The jury weighs the facts and determines if the substance should be treated as a controlled substance analogue. They consider the legal term 'substantially similar' in their deliberation, guided by the trial judge's instructions. To date, the US has had success prosecuting analogue cases as part of the response to the trafficking of these dangerous substances.

Once a substance is deemed a controlled substance analogue, it is treated for the purposes of Federal law as a controlled substance in schedule I.²² The penalties associated with offences involving an analogue are generally determined by referring to the sentencing guidelines for the controlled substance to which it is most closely related. Federal sentencing is driven in large measure by drug type and quantity, so some adjustments may be made for the quantity of the analogue, more or less, needed to produce the same effect on the CNS as the controlled substance²³ it is being compared to.

There are a number of ways that this process might be improved and streamlined. It is resource intensive to send scientists to court to provide expert testimony in almost every case involving an alleged analogue. Likewise, the complexity of these cases requires more intensive involvement by prosecutors. Some means of providing formal or official – and perhaps legally binding – notice of the government's view that a given substance or group of substances meet the definition of an analogue could streamline cases.

²¹ Federal cases may involve a so-called Daubert hearing to determine the admissibility of expert evidence, using the criteria established by the US Supreme Court in the case of *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

²² Title 21, US Code, section 813.

²³ US Sentencing Guidelines, section 2D1.1, Application note 6.

Potential impact on the UK market

Key opportunities

The key opportunities of analogue legislation identified by the Panel were:

- **Supply** – The analogue approach could have a ‘deterrent effect’ on both producers and suppliers who cannot be certain whether a substance that they are making or selling is deemed analogous to a controlled substance. A reduction in supply may lead to reduction in use.
- **Demand** – The possibility of displacement to less harmful substances.
- **Enforcement** – Enforcement agencies could undertake disruptive action against those selling NPS.
- **Harms** – May lead to a reduction in NPS deaths and non-fatal harms if NPS use is reduced and not displaced to other equally, or less harmful, substances.
- **Forensic Science** – No opportunities identified.
- **Legal** – May be opportunities to limit disputes over whether a drug is similar enough to a controlled drug if a central authority determines similarity. It also may avoid the need for formal control and a repetitive scheduling process. So far prosecutions have generally been successful in the US.
- **Communications** – Consistent with current messaging on illicit drugs and theoretically prohibits a large range of substances.
- **Costs** – No opportunities identified.

Key risks

The key risks of analogue legislation identified by the Panel were:

- **Supply** – Legislation may still drive the development of new drugs. This, in turn, may lead to more harmful substances including illicit drugs or new groups of substances being developed. There is also a possibility that NPS controlled under analogue legislation may still be in demand and could increase involvement of organised crime groups and displace sales to the internet. There is no guarantee that this would impact on numbers of headshops who may just diversify into other products.
- **Demand** – There is no certainty whether it will reduce NPS use and, in addition, may drive displacement to alcohol or traditional illicit drugs or prescription medicines.
- **Enforcement** – Cases are often resource intensive for both enforcement and prosecuting authorities. Firstly, the seized drug must be tested and analysed and secondly, there is a need to provide experts to prepare for and offer expert testimony in cases. There will also remain a distinction over controlled and non-controlled drugs.
- **Harms** – If users switched to more harmful substances, this would lead to greater health and social harms.
- **Forensic Science** – Places an additional burden on forensic science providers to identify any organic compound, which will require additional resources and considerable investment. Also without a central authority responsible for determining whether a new substance is an analogue, different providers may come to different decisions as to whether a given substance is an analogue. Commercial providers may not consider this worthwhile.

- **Legal** – This is complex legislation with no formal definition or recognised scientific method to determine whether two substances are ‘substantially similar’. This can lead to an intense ‘battle of experts’ in court and requires judges and/or juries with little scientific background to make a decision over whether a substance is similar enough to a controlled drug to be considered an analogue. Furthermore, whether a drug is a controlled drug analogue will need to be decided on a case-by-case basis by the court, unless a substance is specifically named in the Misuse of Drugs Act 1971. There is a risk that if a case was to be lost, it might send out a message that a product is considered inadvertently authorised.
- **Communications** – This is a complex approach to explain and is unlikely to alleviate any public concern about headshops and other offline retail outlets.
- **Costs** – Likely to be substantial costs as prosecutions will be resource intensive. Additional resource needed to fund the extensive use of experts and also may be increased legal aid costs due to complexity of cases. The costs could be disproportionate to any penalty that a court may impose.

In addition to the opportunities and risks to the UK market as outlined above, it is important to note that most of the countries which currently have an analogue aspect to their legislation do not have generic controls as in the UK, or may not deploy generic controls as extensively as we do in the UK. The environmental factors of the US situation (where analogue legislation is most successful) are substantially different from the UK in many respects: the UK does not have a nationally resourced Drugs Enforcement Agency, nor do we have a national forensic science capability (instead we have commercial forensics operators) and our legal system is not based on a strong plea bargain process.

With all these factors in mind it is doubtful whether in practice the legislation would enhance the current approach enough to justify the increased costs to both enforcement and prosecuting authorities.

Conclusion

Taking into account the opportunities and risks of this approach and the particular UK context, the Panel did not consider that adopting a wider, analogue approach would sufficiently address the requirements set out in the guiding principles to warrant further consideration. The key point identified by the panel was that it would not develop current drug control mechanisms as it does not take the UK much further than its current position in terms of a legislative response to NPS. The approach also would not reduce the visible availability of NPS in the everyday high-street/retail environment. Nor would it minimise the overall costs and complexity to enforcement agencies and others.

Whilst the approach would utilise the existing framework to control drugs and build on it somewhat, this approach could still drive the evolution of new NPS and the risk of successful legal challenge about whether a drug is controlled would remain. Also significant investment would be needed to build the expertise and capability required to successfully implement this approach given the lack of an overarching UK-wide forensic science capability and the lack of a nationally resourced enforcement agency like the DEA.

Nonetheless there were elements of the US analogue approach mainly looking at effect rather than chemical structure of substances, which led the panel to consider the possibility of a neurochemical approach.

B. NEUROCHEMICAL APPROACH

Principle

A neurochemical definition could be introduced into legislation to control drugs based on their effect on the brain. This is different from the current approach of using generic controls which control drugs based on their chemical structure. The Panel considered this primarily as a new method for legislating against synthetic cannabinoids,²⁴ which is an approach recently introduced in both the US and Luxembourg. The Panel was aware of the potential of applying this approach to other groups of NPS. For the purpose of its considerations, it has focused on the application of this approach to the synthetic cannabinoids group for the reasons set out below.

Why is a new approach needed for synthetic cannabinoids?

The use of generic definitions within the Misuse of Drugs Act 1971 has been effective in controlling both large amounts of substances that have been encountered and by anticipating new substances that may occur. This approach, however, has not been as effective for the synthetic cannabinoids where new modifications become available at a rapid rate to circumvent drugs legislation. The UK currently controls around 60% of the synthetic cannabinoids that have been reported to the EMCDDA. For other groups of NPS controlled using generic definitions, we have been able to control over 80–90%.

In addition, the current approach appears to be fuelling the market into producing new variations of synthetic cannabinoids. The Government first accepted the ACMD recommendations to control a large group of synthetic cannabinoids in 2009 and the generic definition had to be further revised in 2012. Within days of the recommendations being published, modifications which fell outside the legislation were being advertised by online suppliers. There are now six ‘third generation’ synthetic cannabinoids that are not controlled under the Misuse of Drugs Act 1971 being regularly encountered on the UK market. The Panel heard that as new generations of synthetic cannabinoids are developed the potency of those substances also tends to increase.

The market in synthetic cannabinoids does not look like it is slowing down. At EU level, the EMCDDA reported 9 new synthetic cannabinoids in 2009, 11 in 2010, 23 in 2011, 30 in 2012 and 29 in 2013. By March 2014 an additional five had been reported (EMCDDA, 2014a).

Synthetic cannabinoids are designed to work in the same way as delta-9-THC, the intoxicant in cannabis. Delta-9-THC acts on specific molecular targets on brain cells called cannabinoid receptors. Two such receptors have been identified, CB1 and CB2. The CB1 receptor is the predominant type in the brain, and evidence clearly indicates that activation of this receptor by delta-9-THC results in the characteristic psychoactive effects of cannabis (Huestis *et al.*, 2001; Iversen 2008).

The extent to which a synthetic cannabinoid acts on and activates the CB1 receptor can be measured through a laboratory-based experiment. The experiment produces a numerical value known as the ‘*K_i*’ value which is a measure of the amount of synthetic cannabinoid required to produce a psychoactive effect.

²⁴ ‘Synthetic cannabinoid’ is the general term used in the report to capture the various chemical groups of this type. The term includes (i) naphthylindoles, (ii) naphthylmethylindoles, (iii) naphthoylpyroles, (iv) naphthylmethylindenes, (v) phenacetylindoles, (vi) cyclohexylphenols, (vii) classical cannabinoids (dibenzopyrans) and (viii) adamantoylindoles.

The lower the K_i value, the lower the amount of synthetic cannabinoid required to produce a psychoactive effect.

Case study: The US Neurochemical Approach

The Expert Panel heard from the US Drug Enforcement Administration (DEA) on the neurochemical approach introduced into their legislation.

The neurochemical approach to controlling NPS was first introduced in the US under the 'Synthetic Drug Abuse Prevention Act 2012' to control synthetic cannabinoids or 'cannabimimetic agents'. The definition used includes a general grouping of substances with possible chemical variations that have a specific effect through binding to the CB1 receptor.

The Act specifically places in Schedule I (the most strictly controlled schedule – substances with high abuse potential with no approved human use) any preparation "... which contains any quantity of cannabimimetic agents, or which contains their salts, isomers and salts of isomers ..." In turn, 'cannabimimetic agents' are defined as:

*"... any substance that is a cannabinoid receptor type I (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following classes ..."*²⁵

The Act further describes 5 groups of synthetic cannabinoids by chemical characteristics of structural classes and lists a further 15 examples of substances that are explicitly controlled by virtue of being placed on the list in the statute. At present, it is necessary to prove both that the chemical meets the structural criteria, as described, and that it satisfies the neurochemical definition. A DEA scientist who consulted with the expert panel advised that the description of characteristics is under-inclusive, and that traffickers have made other variations to produce substances with cannabimimetic effects. The statute's approach could be made more comprehensive and flexible in two ways: (1) by applying it to additionally described groups of synthetic cannabinoids, or, more generically, (2) by eliminating the list of described structural classes, and simply stating that a substance will be deemed controlled simply by virtue of the first prong of the definition, that is, it is a cannabinoid receptor type I (CB1 receptor) agonist as demonstrated by binding studies and functional assays. In so stating, the law would do more by saying less.

The technical work required to implement the neurochemical approach in the US has considerably progressed. Two commercial contracts are in place to undertake the in vitro CB1 testing and the first results on a number of synthetic cannabinoids are expected shortly.

Potential impact on the UK Market

Key opportunities

For the purposes of the review the Panel considered the opportunities and risks of applying a proactive neurochemical approach in the UK context i.e. are not explicitly controlled by virtue of being placed on the list in the statute. This would entail aligning the future control of synthetic cannabinoids with those already controlled as Class B drugs and the full range of offences including possession. The key opportunities of the neurochemical approach identified by the Panel were:

²⁵ Title 21, US Code, section 812(c)(Schedule I), subsection (d).

- **Supply** – Synthetic cannabinoids may be removed from open sale in offline retail outlets. The legislation may get ‘one step ahead’ of the producers and suppliers of synthetic cannabinoids and this may have a deterrent effect that prevents further development and sale.
- **Demand** – There may be a reduction in the use of current, non-controlled synthetic cannabinoids.
- **Enforcement** – The approach would provide powers across enforcement agencies to tackle synthetic cannabinoids.
- **Harms** – There is limited evidence that synthetic cannabinoids are more harmful than herbal cannabis and may be becoming more potent. If use of synthetic cannabinoids reduces, or users displace to herbal cannabis, there may be a reduction in health harms.
- **Forensic Science** – The tests involved in determining the *K_i* value and whether a substance activates the CB1 receptor are relatively cheap and can be done within two to four weeks by suitably equipped laboratories.
- **Legal** – It would reduce the burden on the ACMD, meaning that they could prioritise different groups of NPS. It is better defined than analogue approaches. Any newly approved medical products that act on the CB1 receptor could either be exempted from legislation or accommodated under the Misuse of Drugs Regulations 2001.
- **Communications** – There is a simple message on harm as all synthetic cannabinoids would be illegal.
- **Costs** – There is the possibility to collaborate with other countries which are also introducing this approach to share data and minimise costs.

Key risks

The key risks of the neurochemical approach identified by the Panel were:

- **Supply** – Offline retail outlets would remain open and are likely to promote other types of NPS designed to evade the legislation, and the illicit market may potentially increase production of herbal cannabis. As other countries will not also adopt this approach, development of synthetic cannabinoids is likely to remain. Suppliers could still be driven to develop new products, whether other types of synthetic cannabinoids or other types of NPS, with the risk of driving the market to more potent substances, as may have happened with second and third generation synthetic cannabinoids after generic legislation. Additionally, the legislation may prohibit substances of genuine research interest which would have to be licensed.²⁶
- **Demand** – There is the risk of displacement to other NPS, cannabis and other illicit drugs, prescription drugs, or alcohol.
- **Enforcement** – Enforcement issues for other non-controlled NPS would still remain.

²⁶ In 2013 the Home Office undertook a scoping exercise to assess whether controlled drug legislation is impeding legitimate scientific research in the UK. The scoping exercise was targeted at a cross-section of the scientific community, including the main research bodies. Analysis of responses confirmed a high level of interest, both generally and at institution level in Schedule 1 research. The responses did not support the view that Schedule 1 controlled drug status impedes research in the area. Responses did confirm that Home Office licensing costs and requirements form a part of a number of issues which influence decisions to undertake research in this area; ethics approval was identified as the key consideration, while the next most important was the availability of funding. The majority of respondents also did not consider that the level of controlled drug licence fees restricts valuable research in this area.

- **Harms** – Harms from other NPS would remain, and may increase with displacement. There is also potential for more individuals to be drawn into the criminal justice system. This approach represents a conceptual move in respect of the basis on which the UK drugs policy model has historically been based, moves further away from current drug policy and disconnects with the current process by which individual or families of drugs are risk assessed for health and social harms and brought under the legal framework.
- **Forensic science** – The impact on forensic science depends on the approach to implementation of the provisions. In the absence of a central authority to identify new substances and determine whether they fall under the new controls, the risks are similar to those raised by the analogue approach. Existing forensic science providers do not currently perform Ki tests, and the appetite to provide these would depend on potential commercial returns. It would be possible to contract these out to commercial laboratories which already have this capability. In addition, well characterised samples of the novel materials would have to be sourced for provision to the testing laboratory.
- **Legal** – There is a need for a clear scientific definition in the legislation that would not include any naturally occurring cannabinoids especially those naturally produced in the body (endocannabinoids).²⁷ The process involved in implementing this approach would need to be clearly defined for both enforcement and prosecuting authority. If there is no possession offence then this is inconsistent with current legislation, which makes it an offence to possess drugs which might be as harmful as the types of substance this approach seeks to control.
- **Communications** – The legislation may not be transparent to those without a scientific background. The approach could have negative impact on legitimate medical research into synthetic cannabinoids. This approach could potentially control non-psychoactive substances which may be controversial.
- **Costs** – There will be ongoing costs for testing and reference standards.

The opportunities and risks of this approach would be heavily influenced by the basis on which such an approach could be introduced. The opportunities and risks (unless mitigated) would be maximised if legislation controlled all synthetic cannabinoids that fell within the definition applied. The alternative approach by which cannabinoids continued to be added to Misuse of Drugs Act 1971, albeit following testing rather than consultation and advice from the ACMD, limits the ability to get ahead of developments in the cannabinoid market.

The neurochemical approach has the potential to offer more legal certainty than the analogue legislation, provided a clear and robust definition can be formed. Although there are some inherent risks in terms of controlling a range of substances that may not be widely prevalent in the UK in terms of availability, similar issues are already managed through the use of the UK's generic controls.

²⁷ It should be noted that new cannabinoids are still being found in parts of the body, so there is still not a complete understanding on how this system works.

Conclusion

The Panel agreed that there is potential for an alternative mechanism for controlling synthetic cannabinoids. The proactive neurochemical approach to synthetic cannabinoids meets a number of requirements set out in the guiding principles. These include removing the risk that the legislative response is driving the evolution of synthetic cannabinoids that act on the CB1 receptor, particularly to more potent versions; reducing the pressures on the advisory/control processes under the Misuse of Drugs Act 1971; utilising the existing framework for controlling drugs; responding to the ease of availability of synthetic cannabinoids; and maximising opportunities for compliance and minimising complexity from an enforcement perspective (as all synthetic cannabinoids would be banned).

However, the panel also recognised that there were risks and possible unintended consequences with this approach. This might include increased numbers of users being potentially drawn into the criminal justice system. In addition, there was a possibility that both sellers and consumers might experience difficulties in knowing if a particular NPS or mixture of NPS fell under the terms of the definition. There were also potential risks to research development in an area that may become more important in the future.

It is also important to note that this approach represents a conceptual move in respect of the basis on which the UK drugs policy model has historically been based. A precautionary principle would now be used rather than one of acting proportionately in response to evidence of harm. This is already the case for generic drug legislation but this approach goes further by using a far wider net targeting any synthetic cannabinoid that acts on the CB1 receptor rather than a group of chemicals that have a described structure. Nevertheless, the Panel did not consider that these risks necessarily inherently undermine the model but believed they should be taken into consideration within the overall context of further consideration of an alternative mechanism for controlling synthetic cannabinoids.

Recommendation 2.1: A bespoke approach to tackling synthetic cannabinoids

The Panel recommends that the Government explore the feasibility of an approach to control NPS based on their effects, in this case synthetic cannabinoids, taking into account the need for (i) a robust definition in the legislation; (ii) an implementation process to manage medical products and substances that do not produce psychoactive effects; (iii) the production of reference standards and testing to support any process centrally; (iv) the system implemented to be able to rapidly address the current concerns in keeping up with development (if not streamlined the approach would not work); (v) research to be protected from any potentially negative impacts; (vi) monitoring of possible adverse implications and unintended consequences; and (vii) proactively publishing any results achieved through obtaining reference standards and testing to support the enforcement response.

C. GENERAL PROHIBITION ON THE DISTRIBUTION OF NON-CONTROLLED NPS APPROACH

Principle

Legislation of this type prohibits the supply, importation or exportation of a psychoactive substance that is not specifically controlled under existing legislation or listed as a specific exception. This type of legislation can be framed around further offences including the advertisement and/or sale for commercial gain of substances, with reference to human consumption or not. A substance can be defined as psychoactive or supplied/sold for the purposes of intoxication. It can exclude simple possession offences and/or social supply.

This type of approach is generally intended to tackle or reduce the open availability of NPS and tends to impact most on those individuals who may have easy access to NPS among the general public and do not want to interact with the criminal world. The approach is likely to have different impacts on distinct subgroups of users.

Countries that have used this type of legislation to tackle the trade in NPS include Ireland (see case study), Poland and Romania. These countries have defined psychoactivity in a similar manner – i.e. a substance etc. that stimulates or depresses the central nervous system and is associated with dependency, hallucinations or disturbances in motor function or behaviour. The Romanian law makes use of the term ‘substitute’.²⁸ None of the examples specifies a requirement for ‘harmfulness’ or for a substance to be named within the legislation. However, despite the underlying intent, there are differences. The Irish and the Polish approaches state that the psychoactive effects should be ‘significant’. In the Romanian legislation, there is no requirement to prove intention to benefit or that the product is being used for human consumption. Another key difference is that in Ireland the police enforce the legislation whereas in Poland it is mainly trading standards.

None of the examples of this approach has made it unlawful to possess an NPS.

The Romanian legislation was introduced with an ‘authorisation procedure’ under which a supplier/producer of an NPS can provide documentation to show it is not ‘substituted’. The supplier or producer is required to submit documents including a psychoactive risk assessment and a description of the manufacturing method and caution and safety measures as well as details of physical-chemical, biological or microbiological and toxicological testing. In principle, Romanian authorities can issue an ‘authorisation’ for the approved distribution of the product. The panel found no evidence that the authorisation procedure had been used or instigated.

²⁸ Defined as any natural or synthetic substances or mixture of natural and synthetic, in any physical form, or any product, plant, mushroom or fragments, whose use is not regulated by other legal provisions and is likely to yield psychoactive effects and, which can be used instead of a controlled drug.

Case study: The Irish Criminal Justice (Psychoactive Substances) Act 2010

The Panel heard evidence from the Department of Justice and Equality, Drugs and Organised Crime Unit and from the Garda National Drugs Unit.

The Criminal Justice (Psychoactive Substances) Act 2010 (the 2010 Act) was introduced in response to the proliferation of headshops in Ireland. There were concerns about the potential serious health risks posed from NPS together with a noticeable increase in reporting of psychotic episodes being linked to use of NPS with users reporting to drug treatment services and A&E departments with ill effects.

It came into effect in August 2010 in Ireland and made it a criminal offence to advertise, sell, supply, import or export a psychoactive substance (not otherwise excluded), knowing or being reckless that it was for human consumption. The Act does not contain any offence for possession for personal use of these substances as it is targeted at those involved in trading in NPS rather than users.

A psychoactive substance is defined as a substance that has the capacity to stimulate or depress the central nervous system, resulting in hallucinations, dependence or significant changes to motor function, thinking or behaviour.

The 2010 Act does not deal with substances that are the subject of legitimate trade and focuses exclusively on substances intended for misuse. There are appropriate exemptions for tobacco, alcohol, food and medicines and provision for the further addition of exempted products as deemed appropriate.

The Garda Síochána (Irish Police Force) were given powers to investigate offences and the legislation provides for an escalation through the use of prohibition notices, court issued 'prohibition orders' and 'closure orders' for failure to comply, with non-compliance of a 'prohibition order' punishable by up to five years in prison.

In terms of penalties, any person found guilty of an offence under the 2010 Act (other than under section 15²⁹) is liable on summary conviction, to a fine not exceeding €5,000 or for imprisonment for a term not exceeding 12 months or both; or on conviction on indictment, to a fine or imprisonment for a term not exceeding five years or both.

Where an offence under the 2010 Act is committed by a corporate body and is proved to have been committed with the consent or connivance of, or to be attributable to wilful neglect on the part of any director, manager, secretary or other officer of any corporate body, or a person who was purporting to act in any such capacity, that person or officer will be guilty of an offence and liable to be proceeded against and punished as above.

The courts may, in addition to any other penalty, also order any substance, product, object or any apparatus, equipment or thing to which an offence relates to be forfeited and either destroyed or dealt with in such a manner as the court sees fit.

A Garda inventory of headshops in Ireland indicated that prior to the introduction of the 2010 Act there were 102 headshops. Following the introduction of the 2010 Act, in effect the

²⁹ Any person found guilty of an offence under section 15 of the 2010 Act which relates to obstructing or interfering with a member of the Garda or a customs and excise officer in the course of them exercising their duties under the 2010 Act, is liable on summary conviction to a fine not exceeding €5,000 or imprisonment for a term not exceeding 12 months or both.

headshop trade in Ireland has virtually disappeared with only a negligible amount of such outlets, which continue to be monitored by the police authorities for any breaches of the law.

In tackling online trade in NPS, the Garda National Drug Unit is maintaining an ongoing liaison with the Enforcement Section of the Health Products Regulatory Authority and with the Customs authorities. In this regard the Garda authorities advised (in March 2014) that investigations carried out by all three agencies indicate that Irish domain web pages selling psychoactive substances were not evident at that time.

No formal evaluation of the impact of the legislation has been undertaken but there is ongoing research in this area with concerns expressed by drugs workers about displacement to heroin and prescription drugs, as well as the development of an illegal street market in NPS. However, the numbers of clients attending drug treatment services in respect of problematic NPS use has declined since the introduction of the 2010 Act.³⁰

In terms of prevalence, the results from the National General Population Drugs Prevalence Survey in Ireland currently underway are due in 2015 and these will allow a comparison of trends in NPS use since 2010/2011 (the years in which the previous comparable survey was conducted).³¹

Ireland's Misuse of Drugs Acts 1977 and 1984 remain the primary substance control legislative mechanism in Ireland. In 2010 and 2011, over 200 substances including synthetic cannabinoids were brought under control under that legislation, with the use of generic definitions similar to those introduced in the UK. The Irish Department of Health is also currently developing further regulations which will bring a number of additional NPS under the controls of the Misuse of Drugs legislation.

Potential impacts on the UK market

Key opportunities

The key opportunities of the general prohibition approach identified by the Panel were:

- **Supply** – This approach would be effective at prohibiting the sale of psychoactive substances through offline and UK-based online retail outlets, and as a result removes the availability of NPS by offline retail outlets and reduces the visibility of the market. It also removes the risk that national legislation is a driver for innovation, including to more potent products.
- **Demand** – May be a reduction in NPS use, particularly among those that are unable or unwilling to access internet or criminal suppliers.
- **Enforcement** – This provides clearer enforcement powers to tackle all non-controlled NPS and would reduce the need for trading standards involvement. Would also provide an opportunity to generally prohibit the distribution of NPS.
- **Harms** – This could reduce any anti-social behaviour associated with offline retail outlets. There may also be a reduction in deaths and non-fatal harms from NPS.

³⁰ Data from the Irish National Drug Treatment Reporting System (NDTRS) shows that the number of cases treated for problem use of NPS/'headshop drugs' declined from 368 cases in 2011 to 220 cases in 2012. Of the 220 cases in 2012, 34 were treated for an NPS as a main problem drug.

³¹ A European Commission (2014) Eurobarometer survey of young people aged 15 to 24 year olds reports that 22% of Irish respondents reported using NPS, compared to an EU average of 8%. However, caution is advised, as the sample size in each country is small (500).

- **Forensic science** – The demand for forensic science services will be dependent on the nature of the prohibition, with the smallest burden for an approach that only prohibits the supply for intoxication.
- **Legal** – There is potential scope to allow an exemptions procedure that could enable any newly emerging substances to secure exemptions where benefits can be demonstrated and the risks of health and social harms can be adequately assessed. Definition of psychoactive substance/ for the purposes of intoxication could also capture other more harmful substances that are yet to be controlled, which will prevent sale/supply/ importation/exportation where other specific controls under the Misuse of Drugs Act 1971 are in the process of being brought.
- **Communications** – This approach provides a clearer message as the supply of all NPS will become illegal. It demonstrates that government is addressing public concern over NPS and prohibiting sales by headshops is likely to be popular in areas that have experienced associated problems.
- **Costs** – Apart from resource required for initial action against offline retail outlets, it is likely that any additional costs will be small and could be met from current budgets.

Key risks

The key risks of the general prohibition approach identified by the Panel were:

- **Supply** – Prohibiting sales of NPS by offline retail outlets is likely to result in the market, particularly for popular NPS which are in demand, moving into criminal supply either through internet, international retailers or organised crime and street dealers as happened in the UK with the residual market in mephedrone. In addition, any responsible retail practices e.g. minimum purchase age restrictions employed by headshops will be lost.
- **Demand** – Likelihood of displacement to other substances including alcohol, traditional illicit drugs and prescription medicines.
- **Enforcement** – There is a possibility that longer-term activity may be required, especially if illicit markets develop and possession is criminalised. The opportunity to openly monitor, scrutinise and nudge the market is also reduced. Increased resources potentially needed from an enforcement perspective.
- **Harms** – Health and social harms could increase if there is displacement to more harmful substances. No opportunity for headshops to provide face-to-face harm reduction advice. The explicit link to a response based on (evidence of) harms of NPS is lost.
- **Forensic science** – The risks depend on the nature of the provisions, with an approach that prohibits all psychoactivity placing the greatest burden on forensic service providers. There is a risk that it will create a requirement to identify any organic compound (discussed in relation to the analogue approach). There is also likely to be difficulty in obtaining expert evidence in relation to psychoactivity for substances which have not been tested in animals or humans.
- **Legal** – There is likely to be increased demand on legal services as more substances are controlled. The definition of psychoactivity is likely to be open to legal challenge. Definition of a psychoactive/intoxicating substance could have the possibility of capturing other substances more harmful than controlled drugs where we would not be able to prosecute possession (although we would look to use the Misuse of Drugs Act 1971).
- **Communications** – This may be seen as a simplistic solution to a complex problem and prohibiting sales of all psychoactive substances by headshops may be considered a disproportionate response.

- **Costs** – Loss of tax revenue generated by offline and (UK-based) online retail outlets.

Given the UK's similarity to the Irish legal and criminal justice systems, the Irish legislation gave confidence in terms of the transferability of this approach. Whilst New Zealand (in relation to BZP) and Poland have had much stronger examples of a fall in prevalence following this type of control, their legal and criminal justice systems are not similar and they also have different environmental factors, including geographical considerations in the case of New Zealand, resulting in a much more restricted market in alternative, already controlled psychoactive substances than currently exists in the UK. Furthermore, in the absence of any evaluation of the impact of this legislation, there is no clear evidence on the reduction of drug-related harms. The basis on which any offence would be defined, needs careful consideration in order to mitigate the potential for successful legal challenge i.e. use of a definition of psychoactivity and/or 'for the purpose of intoxication'. The exemptions for the offence, informed by those adopted in the Irish legislation, would need to be carefully examined and allow for expansion as required. The proportionality of applying such an approach in the UK also needs to be carefully considered.

The Panel noted that in implementing the 2010 Act, the Irish legislation allowed for a written notice (prohibition notice) to be served on a person if a member of the Garda (not below the rank of chief superintendent) is of the opinion that the person is, at any place, engaged in the activity of selling, advertising, importing or exporting a psychoactive substance, to direct them to cease selling, advertising, importing, or exporting the substance or object specified in the notice. The 2010 Act also allows for the Garda to apply to the District Court for a 'prohibition order' where a prohibition notice has been served and a member of the Garda not below the rank of superintendent, is of the opinion that the person is not in compliance with a direction contained within the notice. Such a prohibition order would prohibit the named person from engaging in or continuing to engage in the activity of selling, advertising, importing or exporting such substances as may be specified in the order.

If the Government decides to take forward a general prohibition on the sale, supply, importation or exportation of NPS substances, it may wish to consider the need for this type of prohibition notice and prohibition order in the context of the UK.

Conclusion

The Panel agreed that this approach best addressed the key elements of the guiding principles set out for the review, taking into account the opportunities and risks in the particular UK context. It would tackle the NPS market by responding to the ease of availability of NPS in everyday high-street/retail environments; it would remove the risk that the legislative response is driving the evolution of the NPS market, particularly to more potent substances, whilst also maximising opportunities for compliance and minimising complexity from an enforcement and prosecution perspective (as the sale, advertisement, importation or exportation of all psychoactive substances would be banned). The approach would also provide enforcement agencies with the necessary powers to close down any UK-based online retailers of NPS.

However, the Panel also recognised that there were some risks, including whether this type of approach was a proportionate response to the problem of NPS in the UK, and whether, as in the neurochemical approach, this approach represents a conceptual move in respect of the basis on which the UK drugs policy model has historically been based. A precautionary principle would now be used rather than one of acting proportionately in response to evidence of harm. This is already the case to some extent for generic drug legislation but this approach goes further than both the existing legislative response and the proposed approach to tackling synthetic cannabinoids by using a far wider net targeting any psychoactive substance or substance sold for the purposes of intoxication, rather than a group of chemicals that have a described structure. Having said that, the Panel did not consider that these risks necessarily inherently undermine the model but believed they should be taken into consideration within the overall context of a general prohibition on distribution approach and also recognised that the penalties for any controls on psychoactive substances that would result from this kind of approach would be unlikely to be as severe as they are for other classes of drugs controlled under the Misuse of Drugs Act 1971.

Recommendation

Taking into account the opportunities and risks of applying the approach in the UK, the Panel recommends that the Government take forward this approach subject to ensuring that: (i) definitions used in legislation are robust; (ii) required exemptions are addressed (see below); (iii) the approach is focused on tackling the trade or supply rather than personal possession or use; and (iv) potential unintended consequences are explored more fully, building on learning and evidence from countries that have already taken this approach.

In considering the general prohibition on distribution approach, the Panel was mindful that the approach would capture a very wide range of current and potential future psychoactive substances and there was potential for unintended consequences. With that in mind, the Panel recommends that the Government puts in place a schedule of exemptions for substances it wishes to permit when bringing the general prohibition into force (e.g. alcohol, tobacco, caffeine, energy drinks). Furthermore, in designing the legislation, the Government should ensure that provision is made for newly emerging substances to secure exemptions (for example, by a power to add new exemptions by statutory instrument) where the risks of health and social harms can be adequately assessed. A regime is already in place for medicines, but the Government needs to be mindful of the emergence of new markets.

D. FULL REGULATORY APPROACH

Principle

A full regulatory regime would restrict the importation, manufacture, and supply of NPS products and only allow the sale of those substances that can meet manufacturing and safety requirements and are deemed 'low risk'. The legislation would not apply to substances already controlled under the Misuse of Drugs Act 1971; medicines and exemptions could be made for substances such as alcohol and tobacco. The cost for the safety testing (which would include animal and human trials) would be met by the supplier/producer and the decision over whether to approve a product would be made by an expert advisory committee who would evaluate the scientific evidence on a product-by-product basis.

Restrictions, prohibitions and requirements could be placed on approved products including those related to (i) age of a person allowed to buy a product; (ii) place of sale; (iii) advertising, labelling and packaging; and (iv) health warnings, signage, display, storage and record-keeping. Any breach of any of these conditions would be an offence and could lead to a licence being revoked and/or other sanctions and criminal penalties. There could also be a product assessment framework put in place to monitor the safety of the products once approved for sale. Any products that are approved that are later shown to cause harm would be quickly removed from the market.

Case study: The New Zealand Regulatory Approach – The New Psychoactive Substances Act 2013

The expert panel heard from representatives from the Ministry of Health in New Zealand and Dr Chris Wilkins, Massey University, New Zealand.

New Zealand is the only country so far to introduce a regulatory regime that places the onus on manufacturers to prove that their NPS products pose a low risk of harm, prior to receiving approval which allows the products to be legally manufactured and sold.

Under the New Psychoactive Substances Act 2013, manufacturers are required to gain the approval from a Regulator to legally manufacture and sell products containing NPS through providing scientific evidence that the products carry a low risk of harm to users. All approved products will be sold subject to a range of retail restrictions, such as a minimum age of purchase, restrictions on advertising and licensing of sellers. The Ministry of Health predicted that the approval process could take up to 18 to 24 months and cost between 1 and 2 million New Zealand dollars. So far, no products have been granted full approval.

The Act includes information on:

- a regulatory authority within the Ministry of Health to consider and grant approvals of psychoactive products, issue standards and licences and carry out post-marketing monitoring;
- the establishment of an expert advisory committee to give technical advice to the regulatory authority;
- the requirements for importers, manufacturers, wholesalers and retail sellers to apply for a licence;
- the offences and penalties for not meeting the requirements of the Act; and
- the retail restrictions.

Initially, while the new regime is in the transitional phase, the New Zealand Ministry of Health introduced a range of retail restrictions and an interim licensing regime for NPS products that had been on sale six months previously that had not demonstrated any harm to users. In addition, a product safety assessment framework was developed to determine whether or not a product should receive an interim licence. This led to 47 products being granted temporary licences. The initial impact was that the number of NPS retail outlets fell from 3,000–4,000, which were mainly convenience stores, to 156 specialist stores, and the number of legally available NPS products fell from 200 to 47.

In April 2014, all of these temporary licences were revoked by the Ministry of Health following reports of adverse effects from approved products and nuisance and crime around retail stores. At present, no NPS products can be legally sold in New Zealand until the regulations for the full testing process are in place and products can prove that they can pass. At a minimum this is expected to take 12–18 months.

Potential impact on the UK

Key opportunities

The key opportunities of a regulatory regime identified by the Panel were:

- **Supply** – Supply would be limited to approved ‘low risk’ products sold to over-18s in licensed shops; this would encourage responsible retailing, and may reduce the number of irresponsible offline and UK-based online retail outlets.
- **Demand** – There may be reductions in the use of traditional illicit drugs and alcohol if users displace to approved NPS.
- **Enforcement** – There would be a reduced burden on enforcement agencies as the industry may be keen to self-regulate and prevent counterfeit or unauthorised products being sold.
- **Harms** – Harms may decrease as products would be ‘low risk’, pure, have a defined dose, and harm reduction advice could be provided at the point of sale; this reduction could be greater if there was displacement from traditional illicit drugs. An effective pharmacovigilance³² system would allow a quick response to any emergent harms. It would also allow a reduction of harm to users as they would not be criminalised.
- **Forensic science** – Little additional resource required as industry would be required to pay for all product testing.
- **Legal** – The onus of proof is reversed and suppliers have to prove that products are ‘low risk’. There would also be a reduced burden on the criminal justice system and users would not be criminalised.
- **Communications** – Public concern over offline retail outlets may be reduced, as licensing can restrict supply by controlling the density, location and visibility of licensed offline retail outlets. Likely to be popular with those who support drug reform.
- **Costs** – Could be revenue raising, as tax and duty could be charged on NPS products.

³² A system to detect, assess, understand and prevent the adverse effects of drugs.

Key risks

The key challenges of a regulatory regime identified by the Panel were:

- **Supply** – Illicit suppliers of drugs would remain, providing traditional illicit drugs, counterfeit NPS products or smuggled NPS (similar to illicit markets in tobacco and alcohol).
- **Demand** – Use of NPS may increase, as ‘low risk’ products may be perceived as safe and people who would not have previously used illicit drugs may initiate use of approved NPS. ‘Low risk’ products may not appeal to illicit drug users who may continue to use illicit drugs or use in conjunction with NPS. Once demand has been established, it is hard to reduce even when there is evidence of considerable harms (e.g. smoking).
- **Enforcement** – There would be ongoing enforcement for compliance, to stop counterfeiting, and to stop products being exported to countries that prohibit NPS.
- **Harms** – While individual harms may decrease, the total population level harms may increase if there is a large increase in users. It would be difficult to define a ‘low risk’ product, and pre-market testing could not identify long-term health risks, or account for higher risk behaviours such as bingeing, polydrug use, high-risk routes of administration, and use by vulnerable groups. Potential for anti-social behaviour around licensed offline retail outlets.
- **Forensic science** – The requirement would shift from identification of controlled substances to, in effect, pharmaceutical quality control testing including identification and quantification of active ingredients and impurities. Such capability is available but only a small number of existing forensic science providers provide, or could provide, such services.
- **Legal** – There are practical issues with implementation, with a difficult transition from the current situation and a regulated market. There is a legal risk if ‘low risk’ products cause long-term harms, and the industry may resist any measures to improve public health if they impact profitability.
- **Communications** – It is unclear if the general public support this approach, and aspects such as animal testing are likely to be highly unpopular. Illicit drugs would remain controlled, and these may be less harmful than approved NPS. The advertising and availability of NPS, if not adequately controlled, could make them visible to young people which may lead to a confusing message that drug use is safe.
- **Costs** – There would be ongoing costs for monitoring, compliance and pharmacovigilance and there is the potential for increased health costs if long-term harms develop.

The approach taken by New Zealand is both bold and innovative, and fulfils a number of the guiding principles set out for the purposes of the review. However, there are key issues to consider when looking at how it would apply in the UK context. Unique aspects of New Zealand’s position such as geographical factors mean that elements may not be easily transferable to the UK. At present, there is limited evidence to show any effectiveness or impact of this regime and what additional unintended consequences, if any, may exist.

Conclusion

The Panel agreed that the regulatory approach addressed some of requirements set out in the guiding principles in theory. It could potentially reduce harms, protect individuals from risks posed by untested, unknown substances, reduce the ease of availability in an everyday high-street/retail environment as premises would need to be licensed in order to be able to sell approved NPS, would maximise opportunities for compliance and help to develop the evidence base. However, the Panel also expressed concerns about how it would work in practice. The model would not develop an effective and dynamic drug control mechanism by utilising the existing framework for controlling harmful drugs, it would be difficult to define 'low risk' from a legislative and harms perspective, it would not provide a proportionate response, as the infrastructure required to support the approach (following primary legislation) would take 12–18 months to develop based on New Zealand estimates and a mechanism for controlling NPS that were not 'low risk' would still be needed which could lead to confusing messages about NPS overall.

Given that the full regulatory approach is yet to be fully implemented successfully in any country and the other factors outlined above, the Panel calls on the Government to monitor the approach in New Zealand especially in terms of how it impacts on NPS use and any displacement to other substances, how 'low risk' is defined, what products are approved and what monitoring mechanisms are put in place to ensure the safety of users.

E. RESTRICTED AVAILABILITY APPROACH

Principle

A different model from the full regulatory approach, it nonetheless looks to provide a degree of regulation through restrictions around the open sale of non-controlled NPS. Such restrictions might include labelling, advertisement as well as place of sale, age and volume sale restrictions. Offline retail outlets supplying NPS could be licensed in a similar way to sex or betting shops. This type of approach could apply to all non-controlled NPS or certain listed substances similar to the system introduced in New Zealand in 2005 with the use of a Class D category in its Misuse of Drugs Act 1975.

Case study: New Zealand

In 2005, New Zealand, through the Misuse of Drugs Amendment Act 2005, established a regime for regulating psychoactive substances that were not considered sufficiently harmful on the available evidence to justify being controlled drugs. Substances placed in Class D – ‘restricted substances’ would continue to be legally available under the regime but subject to regulatory controls. ‘Restricted substances’ can be manufactured, imported, distributed, sold and used as recreational drugs provided the regulatory controls are complied with. The regulatory controls include:

- prohibitions on the sale or supply of a restricted substance to any person under the age of 18 years;
- prohibitions on the advertising of a restricted substance in the media;
- prohibitions on the sale of restricted substances from premises that sell or supply alcohol to the public or from premises that sell petrol;
- conditions on labelling, packaging, storage and display requirements. Labels on restricted substances must, for example, contain the statement that: “It is illegal to sell or supply a restricted substance to any person under the age of 18”. This statement must also be displayed in all premises selling or supplying restricted substances. Packaging must be tamper-proof and child-proof and restricted substances must be stored or displayed in a manner that does not allow public access; and
- compliance to any Codes of Practice relating to manufactured or imported NPS into New Zealand though no licensing requirements were applied.

The regime was briefly used to regulate BZP which then subsequently became a Class C controlled drug. The schedule has since remained empty.

The use of this type of model with a ‘restricted substances’ or listing regime would need to be based on risk assessments for individual NPS and would not provide a complete regime to deal with all non-controlled NPS, compounding some of the issues with the current approach. The Panel therefore looked at this model in the context of how it might be applied to all non-controlled NPS.

Potential impact on the UK

Some of the opportunities and risks are not dissimilar to a fully regulated market approach. However, the key differences are the absence of any safety testing, and therefore a lack of knowledge on the effects and risks of the NPS products that would be available, and no assurance about the content of NPS products.

Key opportunities

The key opportunities of a restricted availability approach identified by the Panel were:

- **Supply** – Supply would be limited to over-18s in licensed offline retail outlets; this would encourage responsible retailing and could reduce sales from other outlets such as garages.
- **Demand** – There may be reductions in the use of NPS if under-18s can no longer readily purchase NPS, or there may be reductions in the use of traditional illicit drugs and alcohol if users displace to NPS.
- **Enforcement** – There would be a reduced burden on enforcement agencies if retailers complied with the legislation, and clear powers and sanctions to tackle non-compliance.
- **Harms** – Harms may decrease as harm reduction advice could be provided at the point of sale, with appropriate labelling on packaging covering dosage.
- **Forensic science** – There may be a reduced need for testing of products sold by regulated/licensed outlets if retailers complied with the legislation.
- **Legal** – There may be a reduced burden on the criminal justice system by making it easier to take action against those operating outside the licensed/regulated regime if retailers complied with the legislation.
- **Communications** – Public concern over offline retail outlets may be reduced, as licensing can restrict supply by controlling the density, location, visibility and marketing activities of offline retail outlets and other retail outlets could be prohibited from selling NPS. Likely to be popular with those who support drug policy reform.
- **Costs** – The costs of ensuring compliance with the approach could be financed through the application for licence/permits; it could generate revenue as tax and duty would be charged on NPS products.

Key risks

The key challenges of a restricted availability regime identified by the Panel were:

- **Supply** – Fewer offline retail outlets may not result in lower availability and the sale of non-controlled NPS would continue in a high-street setting.
- **Demand** – Use of NPS may increase with the tacit approval of non-controlled NPS with a perception that they are safe and people who would not have previously used illicit drugs may initiate use of NPS.
- **Enforcement** – There would be ongoing compliance enforcement placing an additional statutory responsibility and extra burdens on local authorities if they were responsible for a licensing and compliance regime. Ongoing need for test purchasing in relation to age restrictions on the sale of products and to check whether retailers were adhering to any labelling requirements.

- **Harms** – In the absence of testing and assessment, the harms of NPS are not addressed. In fact, the harms may increase as harmful NPS, potentially more harmful than controlled NPS, could be available and appear to have the tacit approval of the state and therefore be seen as safe. Potential for anti-social behaviour around headshops.
- **Forensic science** – Ongoing need to test and identify controlled and non-controlled NPS.
- **Legal** – There are practical issues with implementation, especially around any labelling provisions, which would need to be fully reconciled with the application of alternative legislation for non-controlled NPS.
- **Communications** – It is unclear if the general public support this approach. The availability of non-controlled NPS, with the tacit approval of use may lead to, or compound, a confusing message that drug use is safe. There may be significant local political opposition to this approach requiring a further response from government. Illicit drugs would remain controlled and these may be less harmful than non-controlled NPS.
- **Costs** – There would be ongoing costs for enforcement against NPS sellers operating outside the new licensing regime, which would not be covered by the fees for licences and there is the potential for increased health costs from both short-term and long-term harms.

This approach would potentially provide the opportunity to encourage ‘responsible retailing’ and does not require the infrastructure for a fully regulated approach, which may be considered to be a more proportionate response to the NPS issue at this time. However, there would continue to be ongoing enforcement activity needed for compliance; in the absence of a quality control regime, there would still be uncertainty about the content and risks of NPS being sold; it is questionable whether this approach would engender public support from those wanting stronger controls. Those wanting wider drug reform may be supportive as it is a break from the current legislative response.

Conclusion

Taking into account the opportunities and risks of the approach and the particular UK context, the Panel did not consider that adopting a restricted availability approach would sufficiently address the requirements set out in the guiding principles. The Panel agreed that the restricted availability approach failed to protect individuals from the risks posed by untested non-controlled NPS. Whilst it provides opportunities for compliance, restricting availability, and the provision of harm reduction advice, it does not fully address the open sale of NPS and sends a confusing message, adding to the perception that NPS are safe. The approach also does not remove the risk that the legislative response is driving the evolution of NPS as there would be a need to continue to control NPS on a substance-by-substance basis.

Chapter 5: Intervention and treatment, prevention and education and information sharing

The emergence of NPS and the limited information around these substances and their harms has made the 'traditional' UK drug scene more complex and fractured than ever before. This situation has several implications for the delivery of the existing pillars of the Government's 2010 Drug Strategy, particularly around treatment service provision, prevention and demand reduction programmes. But a new imperative has also been revealed, the need for a more systematic approach to information exchange at both a national and local level as a tool to ensure practitioners and the public understand these substances and their consequences.

There is already a range of work being undertaken to address these specific challenges. For example:

- **Prevention:** the 'Talk to FRANK' website is used to engage with young people, providing them with reliable and balanced information on drugs. The Government has also undertaken targeted communications campaigns to raise awareness of the risks in taking NPS among young people.
- **Information sharing:** The Drugs Early Warning System (DEWS) provides a platform for sharing information and collating and sharing data from UK and EU drugs early warning systems which can be accessed by health and law enforcement agencies in a timely, evidence-based way.
- **Treatment and interventions** systems are working effectively, with record numbers of individuals in England successfully completing their treatment and with average waiting time to access treatment down to five days. Partners within the sector have responded to the emerging threat of NPS by developing evidence-based clinical guidelines through Project Neptune (NPS UK Network) to cover the assessment and treatment needs of users of NPS, and an increasing number of NPS/club drug clinics have been integrated into existing specialist drug services.

The Panel recognised that the challenges around prevention, treatment and intervention, and information sharing were still ongoing and needed further consideration. The Panel have drawn on existing evidence where available in coming to their recommendations and also recognise that in most cases an NPS-specific intervention is not required, but rather NPS should be built into current systems and approaches.

Three subgroups of the Panel were established to look at the three areas in more detail.

Challenges addressed

Intervention and treatment

Effective intervention and treatment is a key component of the current Drug Strategy. There are already a number of health-related services responding to the harms posed by NPS, including Project Neptune, specialised clinics, young people's substance misuse services, charities and through a number of online resources. There are, however, a number of significant challenges that still exist regarding NPS-related harm that needed to be addressed. These include:

- poor knowledge among some healthcare and drug treatment professionals of harms relating to an ever-increasing number of NPS;
- little systematic recording of NPS harms across the health system;

- despite a strong evidence base for ‘traditional’ drug treatment, there is currently a very limited evidence base relating to the treatment of NPS harms;
- engaging new populations: many NPS users appear discrete from traditional heroin and crack cocaine using populations to which the majority of drug services have been oriented; there is, therefore, a need for many services to consider the use of different engagement strategies to tackle the issue;
- given the limited knowledge of NPS-related issues (harms, using context, populations, engagement strategies, service models and treatment), there is poor knowledge in the field generally, and many are not responding quickly enough to what we do know; and
- challenges in sharing learning across a complex UK health system (and internationally).

Sharing information

The Crime Survey for England and Wales (Home Office, 2013) indicates that use of ‘traditional’ drugs on the UK drug scene has been static or falling since the early 2000s. However, since around 2008, and the rise in the availability of NPS coupled with possibilities for NPS market development via the internet, the UK drug scene has become increasingly complex and fractured. A number of information issues fall out from this, including:

- the difficulty for any one agency to keep abreast of all the new developments;
- the degree of confusion and concern that NPS are causing on the ground including among drug workers, youth workers and teachers;
- the acknowledgement that the Misuse of Drugs Act 1971 needs to be supplemented by other legislation has meant that more professional networks require information including trading standards;
- the management of drug alerts/warnings both within professional groups and those that are public facing;
- the current time lags involved between data collection and publication of data obtained by current networks mean these systems cannot be employed in the service of providing more timely early-warning-type information; and
- the need to collect, analyse and distribute information in a more systematic and timely fashion to help inform policy and practice at both a national and local level.

Prevention and education

Good education and prevention is a critical component of any strategy to reduce the demand for drugs including NPS. In order to enhance our current response in both these areas the following challenges and questions needed to be addressed by the review including how to:

- ensure that NPS are built into wider drug prevention interventions and activities;
- develop an evidence-based public health campaign;
- identify the correct tools/interventions for reducing harm – online and off; and
- reduce investment in prevention and education measures that do not work.

Recommendations

There was clear overlap in the recommendations from all three subgroups.



Therefore the subgroups identified five over-arching themes which reflected the identified issues across all three areas. At the heart of this was the need for further research into NPS, which underpinned the other four themes: (i) data and detection, (ii) sharing information, (iii) skills and workforce, and (iv) expanding the current tool-kit.



Recommendation 3.1: Undertake research in key areas

- 3.1.1** Develop and improve what is currently known about NPS use across the three strands of the Drug Strategy, including information about patterns and motivations of use, harms and data collected from enforcement agencies. This should be considered in both health and wider non-health settings, relating to the general population; specific settings and subgroups; and (potential) problem users including those in touch with criminal justice and health services.
- 3.1.2** Commission research into effective prevention and treatment interventions for NPS.
- 3.1.3** Develop effective preventative campaigns informed by the findings of recommendation 1.1 and including forensic, toxicological and social research data.

Recommendation 3.2: Improve the collection of data and the detection of NPS

There is a need to establish prevalence, evidence and harms associated with NPS. This can be achieved through the following actions and in relation to the three tiers of users in the general population; specific subgroups; and (potential) problem users in touch with criminal justice and health services:

- 3.2.1** Develop detection and data collection tools across criminal justice and health services, and other relevant settings, for example, schools and universities.

3.2.2 Develop understanding of patterns of NPS use in the general population, and in specific subgroups in a range of non-health settings.

Potential Pilot: to pilot a detection tool in areas of high prevalence and with known sub-populations, including a sexual health service, A&E waiting room, criminal justice system and a night-time economy setting.

3.2.3 Develop internet tools to monitor internet activity around NPS.

3.2.4 Record health and social harms related to NPS by utilising professional networks and other early warning systems.

Potential Pilot: to develop and pilot an alert system for clinicians and drugs-outreach workers on NPS and drug-related adverse reactions and harms (similar to the MHRA 'yellow card' system for medication adverse reactions).

3.2.5 Understand local markets, including through headshops, retail outlets, prisons and local police assessment.

Case study: DrugWatch

UK DrugWatch was established in 2010 by a group of professionals working in the UK drugs sector. It is an informal online professional information network aimed at raising or establishing standards for drug information, alerts and warnings. It is currently an unfunded, bottom-up initiative that works in the spirit of mutual co-operation. The group has produced a number of information briefings and other resources for professionals and provided advice around numerous NPS and traditional drugs. It also acts as an advisory body to a number of other professional networks including the Salford Drug Early Warning System pilot.

Recommendation 3.3: Enhance the sharing of information on NPS

Sharing information at both local and national levels is essential in helping to achieve a reduction in the demand and supply of drugs and in promoting comprehensive and effective interventions. The sharing of information on NPS can be enhanced through the following actions:

3.3.1 Local areas should already have a network of practitioners in place through which information can be shared, and should establish one if not already in place.

Potential Pilot: Promote the development of local intelligence networks using a model such as DrugWatch.

3.3.2 Develop a national network of professionals to help record health harms and share information about NPS and other drugs (link to 2.3).

3.3.3 Local and national networks should be used to disseminate effective practice, for example, project NEPTUNE information.

3.3.4 FEWS and DEWS should be used to support networks more widely, where appropriate.

3.3.5 Ensure FRANK continues to develop as a trusted and sober brand, through clear co-operation, partnership and joint learning with NGOs, schools, local public health systems, festival promoters, local media and other agencies.

3.3.6 Work with internet service providers to avoid internet filters that may be developed to target NPS sales inadvertently blocking sites that provide advice and support aimed at reducing harms.

Recommendation 3.4: Skills and workforce: developing competence and support

In order to tackle NPS and drug use effectively we need a competent and confident workforce supported with appropriate, evidence-based tools for assessment and intervention, including:

- 3.4.1** Develop an evaluated programme to ensure that every local area is able to provide an identification and brief advice approach in line with evidence of effectiveness. This will ensure that all staff that come in contact with people using NPS, for example health, law enforcement and education, have access to some basic skills to help identify problematic use and provide brief advice.
- 3.4.2** Staff working in the drugs field should already have the competence to work with the five main drug-effect types/presentations (i.e. stimulant, hallucinogenic, dissociative, sedative or opioid-like, and cannabis-like), and should apply these skills to people using NPS.
- 3.4.3** Given the diversity of the populations using NPS, all staff should be culturally competent in working with specific groups, with additional training provided as appropriate for local populations.

Potential Pilot: Identify the training necessary to ensure that all appropriate healthcare staff (not just drugs workers) are able to identify NPS and drugs issues in their patients.

Case study: The Novel Psychoactive Treatment UK Network – Project NEPTUNE

Through Project NEPTUNE (Novel Psychoactive Treatment: UK Network) the Health Foundation is supporting the development of evidence-based clinical guidelines led by Central and North West London NHS Foundation Trust. These cover the assessment and treatment needs of users of NPS. This guidance includes information on clinical management of harms resulting from acute and chronic use of ‘club drugs’ and novel psychoactive substances (NPS) including intoxication, withdrawal and dependence. The guidance is based on available evidence and clinical consensus. It is a response to the current gap in knowledge and experience in the management of these drugs across the UK and beyond.

Recommendation 3.5: Expanding the tool-kit

Practitioners and the public health workforce require appropriate, evidence-based information and tools for prevention, education, assessment and intervention. The current tool-kit can be expanded through the following actions:

- 3.5.1** It is essential that NPS are addressed as part of a curriculum that helps to build young people’s resilience, whilst noting the limited evidence base on effective programmes. This would be best achieved by Personal, Social, Health and Economic education becoming a statutory subject, which would secure appropriate curriculum time, generate evidence-based tools, raise awareness and drive quality.
- 3.5.2** Schools and other educational settings should continue to be provided with advice and support on evidence-based practice.
- 3.5.3** Schools should be supported with information on the resources that are available to ensure that their drugs policies are in line with best practice and reflect the NPS landscape.
- 3.5.4** Guidance and/or tool-kits should continue to be developed to support local responses and the commissioning of evidence-based prevention across the life course.
- 3.5.5** Support should also be given to local authorities and other commissioners i.e. Police and

Crime Commissioners, to assist planning and commissioning using multi-agency assessments, evidence-based prevention tools and resources such as the Joint Strategic Needs Assessment support pack, to ensure NPS are considered and addressed in local needs assessments and that pathways are always available.

3.5.6 Develop and share evidence-based tools with clinicians for the assessment and management of NPS harms.

Potential Pilot: This could be achieved by piloting particular tools in areas of high prevalence, for example the night-time economy setting.

3.5.7 NPS users should be involved in developing targeted publicity campaigns.

Potential Pilot: Targeted, segmented social marketing campaigns, focused on reducing harms in high-risk groups and settings, within the context of the wider health and social care agenda.

3.5.8 A mechanism should be developed to allow users to easily assess harms posed by drugs including NPS.

Potential Pilot: Develop and pilot an online self-assessment tool to allow users to assess harms. This should be short, confidential and signpost relevant pathways.

Chapter 6: Conclusions including the residual and future challenges

After years of stable and declining drug use, the emergence of NPS has been a ‘game changer’. The appearance of novel substances is not new, and until 2009, most NPS that emerged were typically sold on the illicit market and was an area of limited significance. The open sale of NPS marked the start of what is now called the ‘legal highs’ market. This was facilitated by advances in technology and globalisation. The internet provides a platform for information and wide availability of NPS, which combined with ease of distribution and delivery has also had a significant impact. These factors together with changes in the price, purity and availability of similar traditional illicit drugs created a ‘perfect storm’ for the NPS market to establish itself both in the UK and globally. The range and rate at which new substances appear means that we need to understand and respond differently than we have done in the past.

Consequently, new thinking and a refreshed approach to this issue are timely. The full list of the Panel’s recommendations can be found throughout the report and are summarised in Annex B.

The biggest challenge of NPS is having in place a legislative response that can respond to emerging new substances in a timely and effective way. The Panel considered that the Government’s existing approach under the Misuse of Drugs Act 1971 should be built on, not disregarded. It is within this context that the Panel has recommended that the feasibility of an approach to control NPS under the 1971 Act based on their effects on the brain, in the case of synthetic cannabinoids, is explored.

Notwithstanding this recommendation, the case for an enhanced legislative approach for NPS in general remains. The NPS market is in a constant state of evolution, and in the absence of a comprehensive legal framework, it will remain a low-risk, significant reward enterprise. Whilst there have been developments in the use of non-drug-specific legislation which have disrupted the market to a limited degree, they were not designed for this purpose and so do not provide a complete tool-kit to tackle the availability of non-controlled NPS.

The Panel considered the main options for a different approach, their opportunities and risks in the context of the existing UK infrastructure and systems and an overall assessment against the guiding principles that it adopted.

The Panel’s key legislative recommendation to prohibit the distribution of non-controlled NPS focuses on the supply, rather than those using NPS, and will give law enforcement greater powers to tackle NPS on a general, rather than substance-specific, basis. The Panel was, however, mindful that this is a precautionary approach and a significant step for drug policy. A schedule of exemptions would need to be developed together with a mechanism by which newly emerging substances can be added where risks of harms can be adequately assessed. In assessing the opportunities and risks against the evidence of the problem to be tackled, the Panel’s view was that, on balance, its legislative recommendations provided a response that best satisfied the guiding principles.

The Panel’s clear view was that there is no ‘silver bullet’ approach. A key part of the process for the Panel was recognising the risks and unintended consequences, so that these informed its key recommendations as well as the residual challenges that government and those working in this area will continue to face.

The main residual challenge will be to continue to manage the criminal market, whether through the internet, international retailers or organised crime and street dealers. This may expand if

continuing demand for NPS provides a sufficient incentive, as the propensity of many people to seek psychoactive experiences will continue, which presents its own challenge. The actions recommended by the Panel will not resolve the NPS problem faced in the UK fully but are likely to change its nature. The detail of how the measures are implemented, and how they coordinate with each other, will be very important in determining whether there is net overall benefit or disbenefit from increased control. Adequate monitoring needs to be in place to manage this and other ongoing risks and to mitigate unintended consequences.

The Panel recognised the importance of building on the work of central and local government, the third sector and other providers to enhance the response to the challenges identified in relation to intervention and treatment, prevention and education, as well as information sharing. To help ensure a balanced and comprehensive approach where all strands of the Government's Drug Strategy are invested in, the Panel has made extensive recommendations around these areas. It is important that these recommendations are not developed in isolation from other illicit substances and that existing knowledge and systems that are already in place are built on.

ANNEXES

Annex A: Panel Members and Subgroup Members

Panel Members

Expertise	Panel Member	Position
Enforcement	Commander Simon Bray	National Policing lead for New Psychoactive Substances/Advisory Council on the Misuse of Drugs Member
	Gordon Meldrum (Represented by Lawrence Gibbons)	Director for Organised Crime, National Crime Agency
	Carole Upshall	UK Border Force Director – National Customs Operations and Border Force South Region
Local Authorities	Mark Norris	Senior Policy Adviser, Local Government Association
Forensics	Dr Jeff Adams	Office of the Forensic Science Regulator
Prosecution	Ian Elkins ³³	Senior Strategy and Policy Adviser to the Crown Prosecution Service (CPS)
Medical Science	Professor Les Iversen	Professor in Pharmacology/Chair of the Advisory Council on the Misuse of Drugs
	Dr Owen Bowden Jones	Consultant in Addiction Psychiatry
Social Science/ Academia	Professor Fiona Measham	Professor of Criminology/Advisory Council on the Misuse of Drugs Member
International	Paul Griffiths	Scientific Director, European Monitoring Centre for Drugs and Drug Addiction
Education/ Prevention	Andrew Brown	Director of Policy, Influence and Engagement, DrugScope ³⁴
	Harry Shapiro	Director of Communications and Information, DrugScope

³³ Following his departure from the CPS, Nick Hunt was replaced by Ian Elkins after the Panel's first meeting.

³⁴ At time of his appointment to the Panel, Andrew Brown was Director of Programmes at Mentor (UK).

Subgroup Members

Treatment and Intervention

Dr Owen Bowden-Jones (Chair), Dima Abdulrahim, Annette Dale-Perera, Monty Montcrieff, Kay Orton, Dr John Ramsey, Dr Ann Sullivan, Dr David Wood, Pete Burkinshaw, Jenna Marsh, John McCracken and Karen Rofe

Information Sharing

Harry Shapiro (Chair), Simon Bray, Mark Norris, Ian Goldsborough, Michael Linnell, John Ramsey, Josie Smith, Matt Bullard, Sheila Hardwick, Steve Taylor, Joe Shapiro, Angela Scrutton, Paul Williams and Craig Wright

Education and Prevention

Andrew Brown (Chair), Vivienne Evans, Rick Bradley, Steve Butler, Joe Hayman, Juliet Hillier, Michael Lawrence, Fiona Mackay, Steve Ream, Jeremy Sare, Harry Sumnall, Maryon Stewart and Paul Tuohy

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Harry Matz – Senior Trial Attorney, Narcotic and Dangerous Drug Section, US Department Of Justice

John Scherbenske – Section Chief, Synthetic Drugs and Chemicals, US Drug Enforcement Administration

Mr. Niall Cullen – Drugs and Organised Crime Unit, Department of Justice and Equality, Government of Ireland

Detective Superintendent Stephen Courage – Garda National Drugs Unit, Ireland

Detective Sergeant Brian Roberts – Garda National Drugs Unit, Ireland

Donald Hannah, Don Mackie, Oliver Poppelwell, Adrian Portis (Ministry of Health); **Arati Waldegrave** (Department of the Prime Minister and Cabinet (Health)) – New Zealand Government

Chris Wilkins – Senior Researcher, Massey University, Auckland, New Zealand

Alan Conroy – Barrister, consumer protection, Regulatory and Local Authority Practitioner

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Annex B: Full list of Panel Recommendations

1. Recommendations for existing system

Recommendation 1.1: Building on the UK's balanced approach

The Government should build on its balanced approach to date to tackle NPS that has been wide ranging and has real strength, particularly through the establishment of the Forensic Early Warning System, the use of generic definitions and work on global co-operation and demand reduction, all of which have influenced other countries' own responses.

Recommendation 1.2: Consider extending the temporary class drug order

In consultation with the ACMD, the Government should consider extending the period for which a temporary class drug order can be made, from up to 12 months to 24 months.

Recommendation 1.3: Update local authority guidance on tackling NPS

For the Home Office and local government partners to update the guidance for local authorities, originally published in December 2013, to reflect the latest cases in this area and the developing legal field.

Recommendation 1.4: The Crown Prosecution Service to consider issuing specific guidance on controlled NPS

The Crown Prosecution Service should consider issuing specific guidance to assist prosecutors in addressing the issues that might arise in prosecutions for NPS.

2. Recommendations on legislative response to NPS

There is a case for an enhanced legislative response as the process for controlling drugs remains inherently reactive to developments in the NPS market and, at worst, is driving its development; that whilst there are developments in the use of alternative legislation, there remains an incomplete enforcement tool-kit to tackle the availability of non-controlled NPS.

Recommendation 2.1: A bespoke approach to tackling synthetic cannabinoids

The Panel recommends that the Government explore the feasibility of an approach to control NPS based on their effects, in this case synthetic cannabinoids, taking into account the need for (i) a robust definition in the legislation; (ii) an implementation process to manage medical products and substances that do not produce psychoactive effects; (iii) the production of reference standards and testing to support any process centrally; (iv) the system implemented to be able to rapidly address the current concerns in keeping up with development (if not streamlined the approach would not work); (v) research to be protected from any potentially negative impacts; (vi) monitoring of possible adverse implications and unintended consequences; and (vii) proactively publishing any results achieved through obtaining reference standards and testing to support the enforcement response.

Recommendation 2.2: A general prohibition on the distribution of NPS

Taking into account the opportunities and risks of applying the general prohibition on distribution of NPS approach in the UK, the Panel recommends that the Government take forward this approach subject to ensuring that: (i) definitions used in legislation are robust; (ii) required exemptions are addressed (see below); (iii) the approach is focused on tackling the trade or supply rather than personal possession or use; and (iv) potential unintended consequences are explored more fully, building on learning and evidence from countries which have already taken this approach.

In considering the general prohibition on distribution of NPS approach, the Panel was mindful that the approach would capture a very wide range of current and potential future psychoactive substances and there was potential for unintended consequences. With that in mind, the Panel recommends that the Government puts in place a schedule of exemptions for substances it wishes to permit when bringing the general prohibition into force (e.g. alcohol, tobacco, caffeine, energy drinks). Furthermore, in designing the legislation the Government should ensure that provision is made for newly emerging substances to secure exemptions (for example, by a power to add new exemptions by statutory instrument) where the risks of health and social harms can be adequately assessed. A regime is already in place for medicines but the Government needs to be mindful of the emergence of new markets.

3. Wider recommendations relating to intervention and treatment, prevention and education and information sharing**Recommendation 3.1: Undertake research in key areas**

- 3.1.1** Develop and improve what is currently known about NPS use across the three strands of the Drug Strategy, including information about patterns and motivations of use, harms, and data collected from enforcement agencies. This should be considered in both health and wider non-health settings, relating to the general population; specific settings and subgroups; and (potential) problem users including those in touch with criminal justice and health services.
- 3.1.2** Commission research into effective prevention and treatment interventions for NPS.
- 3.1.3** Develop effective preventative campaigns informed by the findings of recommendation 1.1 and including forensic, toxicological and social research data.

Recommendation 3.2: Improve the collection of data and the detection of NPS

There is a need to establish prevalence, evidence and harms associated with NPS. This can be achieved through the following actions and in relation to the three tiers of users in the general population; specific subgroups; and (potential) problem users in touch with criminal justice and health services:

- 3.2.1** Develop detection and data collection tools across criminal justice and health services, and other relevant settings, for example, schools and universities.
- 3.2.2** Develop understanding of patterns of NPS use in the general population, and in specific subgroups in a range of non-health settings.

Potential Pilot: to pilot a detection tool in areas of high prevalence and with known sub-populations, including a sexual health service, A&E waiting room, criminal justice system and a night-time economy setting.

3.2.3 Develop internet tools to monitor internet activity around NPS.

3.2.4 Record health and social harms related to NPS by utilising professional networks and other early warning systems.

Potential Pilot: to develop and pilot an alert system for clinicians on NPS and drugs-outreach workers on NPS and drug-related adverse reactions and harms (similar to the MHRA 'yellow card' system for medication adverse reactions).

3.2.5 Understand local markets, including through headshops, retail outlets, prisons and local police assessment.

Recommendation 3: Enhance the sharing of information on NPS

Sharing information at both local and national levels is essential in helping to achieve a reduction in the demand and supply of drugs and in promoting comprehensive and effective interventions. The sharing of information on NPS can be enhanced through the following actions:

3.3.1 Local areas should already have a network of practitioners in place through which information can be shared, and should establish one if not already in place.

Potential Pilot: Promote the development of local intelligence networks using a model such as DrugWatch.

3.3.2 Develop a national network of professionals to help record health harms and share information about NPS and other drugs (link to 2.2.3).

3.3.3 Local and national networks should be used to disseminate effective practice, for example, project NEPTUNE information.

3.3.4 FEWS and DEWS should be used to support networks more widely, where appropriate.

3.3.5 Ensure FRANK continues to develop as a trusted and sober brand, through clear co-operation, partnership and joint learning with NGOs, schools, local public health systems, festival promoters, local media and other agencies.

3.3.6 Work with internet service providers to avoid internet filters that may be developed to target NPS sales inadvertently blocking sites that provide advice and support aimed at reducing harms.

Recommendation 3.4: Skills and Workforce: developing competence and support

In order to tackle NPS and drug use effectively we need a competent and confident workforce supported with appropriate, evidence-based tools for assessment and intervention, including:

3.4.1 Develop an evaluated programme to ensure that every local area is able to provide an identification and brief advice approach in line with evidence of effectiveness. This will ensure that all staff that come in contact with people using NPS, for example health, law enforcement and education, have access to some basic skills to help identify problematic use and provide brief advice.

3.4.2 Staff working in the drugs field should already have the competence to work with the five

main drug-effect types/presentations (i.e. stimulant, hallucinogenic, dissociative, sedative or opioid-like, and cannabis-like), and should apply these skills to people using NPS.

- 3.4.3** Given the diversity of the populations using NPS, all staff should be culturally competent in working with specific groups, with additional training provided as appropriate for local populations.

Potential Pilot: Identify the training necessary to ensure that all appropriate healthcare staff (not just drugs workers) are able to identify NPS and drugs issues in their patients.

Recommendation 3.5: Expanding the tool-kit

Practitioners and public health staff require appropriate, evidence-based information and tools for prevention, education, assessment and intervention. The current tool-kit can be expanded through the following actions:

- 3.5.1** It is essential that NPS are addressed as part of a curriculum that helps to build young people's resilience, whilst noting the limited evidence base on effective programmes. This would be best achieved by Personal, Social, Health and Economic education becoming a statutory subject, which would secure appropriate curriculum time, generate evidence-based tools, raise awareness and drive quality.
- 3.5.2** Schools and other educational settings should continue to be provided with advice and support on evidence-based practice.
- 3.5.3** Schools should be supported with information on the resources that are available to ensure that their drugs policies are in line with best practice and reflect the NPS landscape.
- 3.5.4** Guidance and/or tool-kits should continue to be developed to support local responses and the commissioning of evidence-based prevention across the life course.
- 3.5.5** Support should also be given to local authorities and other commissioners i.e. Police and Crime Commissioners, to assist planning and commissioning using multi-agency assessments, evidence-based prevention tools and resources such as the Joint Strategic Needs Assessment support pack, to ensure NPS are considered and addressed in local needs assessments and that pathways are always available.
- 3.5.6** Develop and share evidence-based tools with clinicians for the assessment and management of NPS harms.

Potential Pilot: This could be achieved by piloting particular tools in areas of high prevalence, for example the night-time economy setting.

- 3.5.7** NPS users should be involved in developing targeted publicity campaigns.

Potential Pilot: Targeted, segmented social marketing campaigns, focused on reducing harms in high-risk groups and settings, within the context of the wider health and social care agenda.

- 3.5.8** A mechanism should be developed to allow users to easily assess harms posed by drugs including NPS.

Potential Pilot: Develop and pilot an online self-assessment tool to allow users to assess harms. This should be short, confidential and signpost relevant pathways.

Annex C: Use of alternative legislation to tackle New Psychoactive Substances

Different types of consumer safety laws have been used already in the UK

The **Consumer Protection from Unfair Trading Regulations 2008 (CPUTRs)** broadly seek to protect consumers from misleading behaviour by traders. An important aspect of the regulations is the 'transactional decision test' whereby a trader is in breach of the regulations if the trading of a product 'causes or is likely to cause the average consumer to take a transactional decision he would not have taken otherwise'. The average consumer is defined as someone being reasonably well informed, reasonably observant, circumspect and belonging to the class of consumers towards whom that practice is directed. The difficulty with applying this element of the regulations to NPS is that the relevant class of consumers (substance abusers) are not being misled by packaging describing NPS products as 'plant food' or 'bath salts', and labelling them as 'not for human consumption'. The customers are aware that these labels are false, and would likely buy the NPS products regardless of what was written on the packaging.

There are other elements of the CPUTRs which may have use for the disruption of NPS traders. For instance, it is a breach of the CPUTRs to give the impression that a product can be legally sold when it cannot. This may be applicable if there is reason to suspect controlled substances are being sold, although in such cases a prosecution for supply of a controlled substance under the Misuse of Drugs Act is likely to be more appropriate.

General Product Safety Regulations 2005 (GPSRs) could be applied if a product is deemed unsafe. A 'safe' product is one which presents no or minimal risk 'under normal or foreseeable conditions of use'. It is arguable how readily this applies to products labelled 'not for human consumption', and a prosecution under Regulation 8 of the GPSRs (a breach of which carries a maximum 12 months' imprisonment) would need to demonstrate to the criminal standard that the trader knew or should have reasonably foreseen that the products were going to be consumed. Evidence would also be required to show that the NPS products in question are in fact unsafe, which may be challenging given the paucity of research on many of the substances being sold, and the speed with which the market can shift to new chemicals.

However, the GPSRs also offer a number of other tools which can be useful for disruption: Forfeiture Orders, suspension notices and 'requirements to mark'. Forfeiture Orders are civil orders, and therefore require a lower burden of proof than prosecutions under Regulation 8. These orders only apply to the specific products which the local authority has seized, and therefore are not conducive to a sustainable enforcement response. Suspension notices can also be issued where an enforcement authority has reasonable grounds for suspecting that a requirement of the GPSR has been contravened. These notices forbid the trader from selling the product in question pending the outcome of legal proceedings, such as an application for a Forfeiture Order. Finally, 'requirements to mark' can be used to require particular labelling on NPS products, such as full ingredient lists. These requirements may be difficult for NPS traders to comply with, and therefore requirements to mark can provide grounds for seizing NPS products.

Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (CHIP) require suppliers to identify the hazards (dangers) of the chemicals they supply, give information about the chemicals' hazards to their customers and also to ensure that chemicals are packaged safely. This legislation does not apply to certain substances, such as cosmetics, food and medicines. The panel heard some reports that NPS traders were beginning to produce packaging which appears to be CHIP compliant, making it more difficult for trading standards officers to utilise these

regulations. From 1 June 2015, the CHIP regulations will be replaced by the Classification, Labelling and Packaging Regulation, which will place similar requirements on chemical traders.

The ***Intoxicating Substance Supply Act 1985*** makes it an offence for a person to supply a substance to someone under-18 if the seller knows, or has reasonable cause to believe, that the substance is to be inhaled for the purpose of intoxication. It was designed to prevent minors buying glue and other solvents, but has more recently been used in relation to NPS (see case study below). While it has clear applicability to synthetic cannabinoids (which are smoked), its relevance for other types of NPS, which may be ingested differently, is less certain. It is also clearly limited in that it extends only to sales to under-18s.

Further legislation which may be used to tackle NPS sales

The Local Government Acts 1972 and 2000 both offer possible avenues for local authorities to take out injunctions against NPS traders in their area if doing so would promote the interests and wellbeing of local inhabitants. A court may be more likely to grant an injunction if it can be demonstrated that an NPS trader has failed to take notice of advice or comply with previous rulings, for example rulings under the GPSR to provide safety warnings on packages. A court will be cautious in granting injunctive relief without there being some evidence of attempts by the parties to reach a solution or unless there is a pressing need for immediate protection. It will be down to the court to decide precisely what form an injunction can take (such as enforcing compliance with labelling requirements or insisting sales can only be made in line with other legal requirements). However, breaching such an injunction could constitute contempt of court, the penalty for which can be up to two years in prison.

Case study: West Yorkshire Police using the Intoxicating Substances (Supply) Act

In January 2013, West Yorkshire Police conducted surveillance on a market stall within Kirkgate market and saw purchases of synthetic cannabinoids by a 16-year-old boy. Both the seller and stall-holder were arrested and charged with an offence under the Intoxicating Substances (Supply) Act. The seller admitted the offence, while the stall-owner denied the offence on the grounds that he had not actually sold the item to the boy. He was subsequently convicted on the basis that he bore legal responsibility for the actions of his staff. Both were given a conditional discharge.

Case study: Belfast City Council using the General Product Safety Regulations

In February 2014, Belfast City Council was granted a Forfeiture Order under the General Product Safety Regulations for NPS products seized from a shop, on the grounds that the products did not meet the required safety standards under these regulations. This followed a coordinated operation between the council and the Police Service of Northern Ireland targeting the five shops identified as selling NPS in Belfast. The other four shops voluntarily agreed to stop selling NPS. The shops in Belfast were believed to be contributing to increased reports of anti-social behaviour connected with individuals ingesting NPS products in public places in the city centre. The innovative work of Belfast City Council has informed the efforts of other local authorities across the country.

Annex D: Model Impact Framework

This annex builds on Chapter 4 of the Panel's report, and provides more detail on the Panel's views of the potential risks and opportunities presented by the different legislative approaches to tackle NPS. The Panel also described their views on the baseline situation in the UK, and identified the potential opportunities and risks of the UK's current approach. Therefore, when references are made to increases or decreases, these relate to potential changes relative to the UK's current approach. A description of the common criteria chosen for the model impact framework can be found in Box 1.

The views come from across the spectrum of Panel members, so there are contradictory statements. It is important to note that the Panel identified **potential** opportunities and risks, and these may not be actualised if the legislative approaches were implemented in the UK. The opportunities and risks identified have not been ranked by their likelihood or their importance. The Panel was mindful that as these approaches have not been implemented in the UK, it is difficult to fully predict their impact, and there may be unintended consequences that have not been identified.

In some instances, factors have been identified that could be viewed as both opportunities and risks. For example, if displacement to alcohol happened as a consequence of an approach, theoretically, this could increase or decrease total harms depending on the level of alcohol consumption and the type of substance it displaced. When this is the case these factors have been included in both columns.

The panel identified five main options for enhancing the UK's current approach: an analogue approach, a neurochemical approach, a general prohibition on the distribution of non-controlled NPS (blanket ban), a fully regulated model and a restricted availability approach. These legislative options, alongside the UK's current approach, are tested against the criteria of the impact framework.

Box 1: Descriptions of the criteria chosen for the NPS Impact Framework

The supply chain – The impact across different suppliers of NPS and illicit drugs was covered, including headshops and other online and offline retailers. When the legislation involved additional prohibition, consideration was given to the likelihood of displacement to other routes of supply, such as the ‘darkweb’ and organised crime groups (OCGs). Also included was the role of legislation in driving the development of NPS.

Demand – Changes to the demand for NPS, with distinctions being made if this was likely to vary across different user groups. Displacement was also covered, with the possibility of legislation driving displacement to or displacement from: illicit drugs, other NPS, prescription drugs and alcohol.

Harms – The impact on a variety of different health and social harms, including: acute and chronic health harms such as deaths, non-fatal intoxications and treatment entrants, alongside social harms such as crime and anti-social behaviour. The conceptual basis of the legislation was also considered.

Enforcement – The impact on enforcement agencies including the Police, Border Force, the National Crime Agency and Trading Standards. Distinctions were made between reactive (responding to the market in NPS) or proactive (ahead of the market in NPS) approaches.

Forensic science – The impact on Forensic Science Providers (FSPs), covering issues such as how demand for forensic science services would change, and whether the commercial market in forensic science services would respond to these changes.

Legal services – How the legislation would affect the criminal justice system, specifically how the legislation would function in the courts, and whether the legislation would be open to legal challenge.

Associated costs – Costs across the full range of other criteria including the impact on government agencies, the healthcare system, the criminal justice system, forensic science providers and NPS retailers. Changes to revenue through duty and taxes were also considered.

Messaging and communications – How the legislative options would fit into the wider context of messaging on traditional illicit drugs, how the media were likely to report the legislation and whether the legislation would command public support.

Current UK Approach

Theme	Opportunities	Risks
Supply	<ul style="list-style-type: none"> • Voluntary compliance among retailers – with incentives for retailers to supply quality products, and cease to supply controlled drugs • Limited involvement of organised crime groups • Relatively pure products, although some products can contain controlled drugs 	<ul style="list-style-type: none"> • Increasing rate of new NPS being detected in the EU • Legislation may be driving the development of new, and potentially more dangerous, NPS • NPS for sale on the high street in headshops – highly profitable and visible business • Clearance sales before NPS are controlled
Demand	<ul style="list-style-type: none"> • Use of most NPS remains low compared to traditional illicit drugs • Most users of NPS are also users of traditional illicit drugs 	<ul style="list-style-type: none"> • Overall level of NPS prevalence is unclear • There are specific groups with high prevalence – clubbers, psychonauts, men who have sex with men, disadvantaged teenagers, prisoners
Enforcement	<ul style="list-style-type: none"> • With the exception of possession, all Misuse of Drugs Act 1971 (MDA) offences apply to Temporary Class Drugs (TCDs) • Limited burden on enforcement agencies as activity against NPS is generally low compared to activity against traditional illicit drugs 	<ul style="list-style-type: none"> • Reactive approach • Difficult for enforcement agencies to distinguish between controlled drugs, TCDs and non-controlled NPS in practice • More controls, more offences to enforce and there are limited resources across enforcement agencies • Difficult to take enforcement action against non-controlled NPS
Harms	<ul style="list-style-type: none"> • Deaths from NPS remain low compared to illicit drugs • Social harms are potentially low and may be comparable to the drugs NPS imitate • Does not criminalise users for possession of TCDs 	<ul style="list-style-type: none"> • Increases in deaths and poison centre reports • Limited data on long-term harms, acute toxicity and A&E admissions • May drive development of more dangerous NPS • Knowledge time lag – constant development of new NPS leads to professionals and users playing catch-up on potency and harms

Current UK Approach

Theme	Opportunities	Risks
Forensic Science	<ul style="list-style-type: none"> • Testing covered under most current contracts with Forensic Science Providers (FSPs) • Forensic Early Warning System (FEWS) provides support to FSPs with reference standards and up-skilling • Testing does not need to prove psychoactivity, only that the sample is a controlled drug 	<ul style="list-style-type: none"> • Enforcement agencies have limited front-line capability to test and identify NPS • More complex samples need more complicated and expensive tests to identify, some FSPs do not have these capabilities • The commercial market for FSPs has a lack of incentives to develop NPS testing
Legal	<ul style="list-style-type: none"> • Minimal challenge for experts in prosecutions • There have been no legal challenges to temporary class drugs orders (TCDOs) or generic definitions • Low volume of prosecutions for TCDO offences • Fits in well with EU system 	<ul style="list-style-type: none"> • Difficult to prosecute suppliers of non-controlled drugs • Alternative legislation (General Product Safety Regulations, Intoxicating Substances Supply Act) is not designed for tackling NPS • Resource intensive for trading standards to pursue prosecutions under consumer protection legislation • Experts sometimes needed for product safety prosecutions, may not be available • Use of statutory defence based on lack of knowledge
Messaging and Communications	<ul style="list-style-type: none"> • High volume of media coverage provides a good messaging opportunity • Opportunity to nudge users away from the most harmful NPS • The Misuse of Drugs Act 1971 and ABC classification is well understood by media • Desire among treatment and education workforce to learn more about NPS 	<ul style="list-style-type: none"> • Media concern over NPS can inadvertently publicise and promote products • Confusing message as due to distinction between controlled and non-controlled drugs • There may be a perception that legal drugs are safe • Detailed discussion on online forums presents challenges to getting information and messaging across
Costs	<ul style="list-style-type: none"> • Costs for enforcement agencies generally small compared to ongoing work on traditional illicit drugs 	<ul style="list-style-type: none"> • Potential for increased costs if a very dangerous NPS becomes prevalent • Unknown current and future health and social costs • Enforcement agencies have to pay for costly forensic testing

Current UK Approach

Theme	Opportunities	Risks
Supply	<ul style="list-style-type: none"> Potential for a reduction in supply due to deterrent effect 	<ul style="list-style-type: none"> There is no legal certainty that new substances are illegal Legislation is still driving the development of new NPS, may lead to more harmful substances No guarantee that headshops will close as they may diversify into other products There may be illicit supply of NPS by organised crime groups, or through the internet
Demand	<ul style="list-style-type: none"> Potential for displacement to alcohol or other less harmful substances Reduction in supply of NPS may lead to reduction in the use of NPS 	<ul style="list-style-type: none"> Unclear if analogue approach actually reduces NPS use Potential for displacement to traditional illicit drugs, alcohol or prescription medicines
Enforcement	<ul style="list-style-type: none"> Aggressive enforcement may increase the deterrent effect May settle down over time into a stable position Uncertainty over legality may deter suppliers as they cannot guarantee that a product is legal Once legal issues are worked through, fairly comprehensive definition that prohibits wide range of substances 	<ul style="list-style-type: none"> Analogue cases are very resource intensive for both enforcement and prosecuting authorities Distinction remains over controlled and non-controlled drugs Uncertainty over similarity until proven in court No guarantee that enforcement agencies will use new powers
Harms	<ul style="list-style-type: none"> Possible reduction in deaths and non-fatal harms from NPS 	<ul style="list-style-type: none"> Displacement to more harmful illicit drugs could increase harms Development of more harmful NPS could increase harms Potential for health and social harms if displacement to alcohol

Analogue Approach

Theme	Opportunities	Risks
Forensic Science	<ul style="list-style-type: none"> No forensic opportunities have been identified for the analogue approach 	<ul style="list-style-type: none"> Increased demand for experts Different FSPs may come to different decisions on similarity Some FSPs may be unwilling to comment on similarity Requirement of more advanced analytical capability to determine exact substances, requires additional resources and investment
Legal	<ul style="list-style-type: none"> Battle of experts less likely if central authority determines similarity May avoid the need for formal controls and repetitive scheduling of NPS Prosecutions are generally successful in the USA, but UK legal system is different to USA 	<ul style="list-style-type: none"> Likelihood that cases will be disputed resulting in battle of experts Need to prove similarity in structure and effect Time consuming as expert testimony needed to prove similarity for each substance If a case is lost, and an NPS deemed not to be an analogue, then this may send a message that a NPS has been inadvertently authorised Complexity of legislation
Messaging and Communications	<ul style="list-style-type: none"> Despite practical limitations, analogue legislation theoretically prohibits a large amount of psychoactive drugs Consistent with current messaging on illicit drugs 	<ul style="list-style-type: none"> Public concern around NPS, headshops and other online and offline retailers could remain Complex approach to explain
Costs	<ul style="list-style-type: none"> No cost opportunities have been identified for the analogue approach 	<ul style="list-style-type: none"> Prosecutions are very resource intensive Increase in prosecution and defence costs due to extensive need for experts Increased legal-aid costs due to complexity of cases

Neurochemical (in relation to synthetic cannabinoids) Approach

Theme	Opportunities	Risks
Supply	<ul style="list-style-type: none"> • Reduction in synthetic cannabinoid products (smoking blends etc.) • Synthetic cannabinoid products may be removed from open sale in headshops and other offline retail outlets • Removal of synthetic cannabinoids would negatively impact headshop profitability • Potential deterrent effect • Largely removes UK legislation as driver of innovation in synthetic cannabinoids (however, as the same approach is not taken internationally, the development incentive remains for these other markets) 	<ul style="list-style-type: none"> • Headshops, offline retail outlets and online retailers remain open, may promote other NPS • Other types of NPS still available • Products may be developed if they can evade legislation (e.g. pro-drugs or endocannabinoids) • Inclusion of non-psychoactive drugs • Inclusion of substances of genuine research interest • Increased herbal cannabis production to cover increased demand • If the approach relies on the use of <i>Ki</i> value threshold products that fall below this value may be marketed • If system is reactive, it may speed up development of synthetic cannabinoids
Demand	<ul style="list-style-type: none"> • There could be a reduction in use of currently non-controlled synthetic cannabinoids 	<ul style="list-style-type: none"> • Potential for displacement to herbal cannabis • Potential for displacement to other types of NPS (stimulants, hallucinogens, opioids)
Enforcement	<ul style="list-style-type: none"> • Provides powers across enforcement agencies to tackle synthetic cannabinoids as a group 	<ul style="list-style-type: none"> • If the system is reactive, it needs to be sufficiently prompt to remove any opportunity to market and profit from synthetic cannabinoids, or to deter those who may market new synthetic cannabinoids • Enforcement still problematic as some substances not controlled • Training need to ensure officers are aware of which products are controlled • More enforcement needed if herbal cannabis production and use increases • No guarantee that enforcement agencies will use new powers

Neurochemical (in relation to synthetic cannabinoids) Approach

Theme	Opportunities	Risks
Harms	<ul style="list-style-type: none"> Potential reduction in harm if users displace from high-potency synthetic cannabinoids to lower-potency herbal cannabis, or if they stop using entirely 	<ul style="list-style-type: none"> Most NPS-related deaths are not related to synthetic cannabinoids. Deaths from other NPS would continue, and may increase with displacement Potential for more individuals to come in contact with the criminal justice system Could represent a conceptual move away from the process by which individual drugs are risk assessed and controlled on the basis of their health and social harms. However, generic definitions have already moved away from risk assessing individual drugs, and there is a body of evidence on the harms of synthetic cannabinoids as a category
Forensic Science	<ul style="list-style-type: none"> Cheap and fast (two to four weeks) tests to determine CB1 binding and <i>K_i</i> value 	<ul style="list-style-type: none"> A system to test synthetic cannabinoids needs to be established Need to develop costly reference standards As determining CB1 activity and <i>K_i</i> values is a new capability, FSPs may be unwilling to take on this work unless it is commercially viable Uncertainty over partial binding and antagonists
Legal	<ul style="list-style-type: none"> Less need for experts in court compared to analogue approach Reduced burden on the ACMD, giving them more time to spend on assessing other groups of NPS Better defined than an analogue approach Any newly approved medical products that act on the CB1 receptor could be exempted from legislation or accommodated under the Misuse of Drugs Regulations 2001 	<ul style="list-style-type: none"> Experts may still be required, depending on wording of legislation, and to determine exemptions If there is no possession offence, this is inconsistent with current legislation on synthetic cannabinoids Approach is only pro-active if synthetic cannabinoids are inherently illegal; if they need to be tested first then it is still reactive Need for a clear definition that excludes endocannabinoids

Neurochemical (in relation to synthetic cannabinoids) Approach

Theme	Opportunities	Risks
Messaging and Communications	<ul style="list-style-type: none"> • Innovative approach, chance for UK to lead the way • Simple message as all synthetic cannabinoids are illegal 	<ul style="list-style-type: none"> • Moves the focus away from the harms of the individual drugs – CB1 binding does not directly equate to harm • Need to explain the complexity of approach (particularly the underlying science) and why the UK taking a new approach • The inclusion of non-psychoactive substances may be controversial, although this may already happen with generic definitions • May be controversial – CB1 receptors are distributed throughout the body and activity is not well understood • Within the existing licensing regime, there may be a need for more licences for legitimate research into cannabinoids, as this approach brings more into more substances in scope
Costs	<ul style="list-style-type: none"> • Possibility of international collaboration to share data and minimise costs 	<ul style="list-style-type: none"> • Ongoing costs for testing and reference standards

General Prohibition on the Distribution of Non-controlled NPS Approach

Theme	Opportunities	Risks
Supply	<ul style="list-style-type: none"> • Reduction in availability and supply of NPS as headshops, other offline retailers, and UK-based online retailers could no longer legally supply them • May lead to the closure of headshops due to reduced profit as they could not sell NPS. Consequently this would make NPS less visible • UK legislation no longer a driver of innovation; however, international situation may still drive development • Organised crime groups unlikely to supply NPS that have limited or marginal popularity 	<ul style="list-style-type: none"> • There may be displacement to the internet – overseas retailers, darkweb and social media • Loss of any responsible retail practices (e.g. purchase age restrictions) that may have existed in headshops • Less effective against non-specialist retailers (e.g. newsagents and corner shops), as they could be selling covertly, or may not be aware of laws • The residual demand for popular NPS (e.g. mephedrone) can only be supplied by organised crime groups and street dealers • Greater variability of purity of NPS in illicit market, so harder for users to dose accurately • NPS may be used as cutting agents in illicit drugs • ‘Non-psychoactive’ NPS may be marketed, and these may be psychoactive • NPS may be legal if sold for other purposes (e.g. cognitive enhancers), and other loopholes unknown
Demand	<ul style="list-style-type: none"> • Potential for a reduction in use of currently non-controlled NPS • Reduction may be higher in those who are unable or unwilling to access internet or criminal supplies, e.g. school children or professionals • There could be displacement to alcohol 	<ul style="list-style-type: none"> • Potential for displacement to traditional illicit drugs, alcohol or prescription medicines • Users may make contact with illegal suppliers

General Prohibition on the Distribution of Non-controlled NPS Approach

Theme	Opportunities	Risks
Enforcement	<ul style="list-style-type: none"> • Pro-active • Opportunity for voluntary one-off shutdown of NPS retailers, with retailers surrendering NPS to enforcement agencies • Simplified enforcement as all substances controlled • Reduced need for trading standards involvement • Enforcement may have a positive impact on communities 	<ul style="list-style-type: none"> • Longer-term activity may be needed, particularly if illicit markets develop • Greater burden if possession is criminalised • No longer able to openly monitor, scrutinise and nudge market • No guarantee that enforcement agencies will use new powers • Enforcement may have a negative impact on communities
Harms	<ul style="list-style-type: none"> • Possible reduction in deaths and non-fatal harms from NPS • Reduction in possible anti-social behaviour associated with offline retail outlets • There may be no overall increase in organised crime groups activity, as it is unlikely that new organised crime groups would form to supply NPS, and NPS may be absorbed into the activities of current organised crime groups 	<ul style="list-style-type: none"> • Drugs are no longer controlled on the basis of evidence of harms • Potential for health and social harms if there is displacement to more harmful drugs and alcohol • There could be a short-term spike in harms if retailers have clearance sales • Variable purity and use of cutting agents • Increased harms from involvement of organised crime groups • Face-to-face interaction between retailers and users lost, cannot provide harm reduction advice • If weak NPS are marketed, users may switch to injecting to maximise effect
Forensic Science	<ul style="list-style-type: none"> • Demand for forensic science services is dependent on wording of general prohibition on distribution (blanket ban) approach – prohibiting supply for intoxication would create less demand than a ban on possession? 	<ul style="list-style-type: none"> • Determining psychoactivity is likely to be slower and more expensive than the current work of FSPs • FSPs may be unwilling to take on extra work • There may be insufficient capacity to fill the increased requirement for pharmacologists

General Prohibition on the Distribution of Non-controlled NPS Approach

Theme	Opportunities	Risks
Legal	<ul style="list-style-type: none"> • Simple – not as complex as the different legislative options currently available (e.g. Intoxicating Substances Supply Act, General Product Safety Regulations and other consumer protection legislation) • An authorisation procedure could allow any future legitimate products to be approved • Definition of ‘psychoactive substance’ or ‘supply for the purposes of intoxication’ could also capture other harmful substances that are yet to be controlled 	<ul style="list-style-type: none"> • Potential for increased demand on legal services as more substances are controlled • Use of a definition of psychoactivity could be open to legal challenge • Difficult to define sales ‘for the purpose of intoxication’ • Courts could reach different decisions on the illegality of a drug (e.g. two simultaneous cases reaching different verdicts) • Exemptions may not cover all legitimate products
Messaging and Communications	<ul style="list-style-type: none"> • Tackling headshops/offline retail outlets is likely to be popular in areas with local problems • Government is addressing public concern over ‘legal highs’ • Clear message on harms of NPS as supplying them is no longer legal • NPS communications campaigns could be merged into existing work on illicit drugs • Removal of distinction between controlled and non-controlled drugs 	<ul style="list-style-type: none"> • A general prohibition on distribution (blanket ban) approach may be seen as a simplistic response to a complex problem • As NPS evidence base is weak, it may be problematic to justify this approach on the basis of harms • Legality is no longer directly linked to harm • The extent that this leads to closure of headshops may be seen as a disproportionate response • Government response may be framed as a response to a moral panic
Costs	<ul style="list-style-type: none"> • Aside from an initial seizure of NPS, ongoing work could be met from current budgets • Reduction in trading standards costs, although current NPS activity is low 	<ul style="list-style-type: none"> • Potential for increased costs for enforcement agencies and wider criminal justice system • Reduced tax from NPS sales • Costs could increase if loopholes are found

Fully Regulated Approach

Theme	Opportunities	Risks
Supply	<ul style="list-style-type: none"> • Supply would be limited to approved products in licensed shops and restricted to over-18s • Only 'low-risk' products available • Availability, density, location and visibility of NPS retailers could be controlled • Face-to-face service • Licences could be revoked for non-compliance with legislation • Reduced profit for organised crime groups 	<ul style="list-style-type: none"> • Fewer outlets and products may not result in lower availability • Illicit supply could remain, providing traditional illicit drugs, counterfeit or controlled NPS products, or smuggled NPS (similar to illicit market in alcohol and tobacco, which provides counterfeit and smuggled products, despite the availability of legal supplies) • Limited control over marketing on social media and overseas websites
Demand	<ul style="list-style-type: none"> • There could be a reduction in traditional illicit drug use through displacement to approved NPS • There could be a reduction in alcohol use through displacement to approved NPS 	<ul style="list-style-type: none"> • Use of approved NPS may increase • 'Low-risk' products may not appeal to traditional illicit drug users • People who did not previously use illicit drugs may initiate use of approved NPS • Under-18s could still acquire NPS through proxy-purchasing • Once demand is established, it is hard to reduce it even when there is evidence of considerable harm (e.g. smoking) • Approved NPS may potentially act as gateway drugs to illicit drugs
Enforcement	<ul style="list-style-type: none"> • Self-regulation – NPS 'industry' keen to prevent counterfeit or unauthorised products affecting their profits or reputation • Reduced burden on all enforcement agencies 	<ul style="list-style-type: none"> • Resources and time would be needed to establish a regulatory body • Ongoing enforcement activity to ensure compliance • Export market may develop, with products being shipped to countries that control all NPS • Enforcement required to tackle counterfeit products • Test purchases needed to enforce regulations such as restriction on under-18s

Fully Regulated Approach

Theme	Opportunities	Risks
Harms	<ul style="list-style-type: none"> • Pure products with defined doses • Clinical trials to prove ‘low risk’ of harm; however, ‘low risk’ needs defining • Harm reduction advice may be provided at point of sale – dosage, side effects, and contraindications • Displacement from harmful illicit drugs to ‘low-risk’ NPS may reduce the harms from illicit drugs • Does not criminalise users • Effective system of pharmacovigilance could allow a quick response to any emergent harms 	<ul style="list-style-type: none"> • Increased use could result in increased total aggregate harms even with ‘low-risk’ product • Binging, alcohol use, polydrug use, and injecting, and existing health problems will increase the harms from ‘low-risk’ NPS use, and are hard to test for • Difficult to prove long-term safety before products are marketed • Potential crime and disorder around approved retailers • Different harms depending on how ‘low risk’ is defined – medical standards or same as alcohol and tobacco?
Forensic Science	<ul style="list-style-type: none"> • Industry would pay for product safety testing; however, any illicit products would not be tested 	<ul style="list-style-type: none"> • Industry-funded testing may be subject to bias; however, government could fund testing to avoid this • FSPs are not configured to test for product safety
Legal	<ul style="list-style-type: none"> • Reduced burden on criminal justice system • Does not criminalise users or communities • Reverses onus of proof – suppliers have to prove ‘low risk’ 	<ul style="list-style-type: none"> • ‘NPS industry’ may resist measures to improve public health if they affect profitability • Legal risk if ‘low-risk’ products cause long-term harms • Challenges to licensing process • Practical issues with implementation, difficult transition between current situation and regulated market

Fully Regulated Approach

Theme	Opportunities	Risks
Messaging and Communications	<ul style="list-style-type: none"> • Likely to be popular among drug-reform campaigners • Increased credibility for Misuse of Drugs Act if different levels of harm are acknowledged • Marketing activities of NPS retailers can be regulated • Harm reduction messages on product packaging • Public concern over offline retail outlets may be reduced, as regulation can control the density, location and visibility of these outlets 	<ul style="list-style-type: none"> • Potentially controversial – unclear if public support this approach • Distinction between controlled and non-controlled drugs remain • Illicit drugs would remain controlled, and these may be less harmful than approved NPS • ‘Low risk’ might be interpreted as safe • Currently controlled drugs may be less harmful than those approved for sale • Animal testing likely to be highly unpopular • Products may be aggressively marketed • Advertising and availability of NPS could make them visible to young people, and send a confusing message on the safety of drug use
Costs	<ul style="list-style-type: none"> • Revenue generating as tax and duty could be charged on NPS products • Possible reduction in criminal justice system costs 	<ul style="list-style-type: none"> • Potential for increased health costs if long-term harms develop • Funding needed for pharmacovigilance system • Ongoing monitoring for compliance

Restricted Availability

Theme	Opportunities	Risks
Supply	<ul style="list-style-type: none"> Supply would be limited to licensed shops Restricted to over-18s Face-to-face service Licences could be revoked for non-compliance with legislation Availability, density, location and visibility could be controlled 	<ul style="list-style-type: none"> Fewer outlets and products may not result in lower availability The sale of untested non-controlled NPS in a high-street setting would continue Illicit supply would remain, providing traditional illicit drugs and controlled NPS
Demand	<ul style="list-style-type: none"> There may be a reduction in the use of NPS among under-18s, as they would be prohibited from purchasing NPS There may be a reduction in the use of illicit drugs and alcohol if users displace to NPS 	<ul style="list-style-type: none"> Under-18s could still acquire NPS through proxy-purchasing The overall use of NPS may increase, particularly among those who do not use traditional illicit drugs, as licensing may provide tacit approval and a perception of safety
Enforcement	<ul style="list-style-type: none"> There would be a reduced burden on enforcement agencies if retailers complied with legislation Clear powers and sanctions to tackle non-compliance 	<ul style="list-style-type: none"> There would be an additional burden on local authorities if they had statutory responsibility for the licensing and compliance regimes Ongoing enforcement activity to ensure compliance Test purchases needed to enforce restriction on under-18s
Harms	<ul style="list-style-type: none"> Harm reduction advice could be provided at point of sale 	<ul style="list-style-type: none"> As products are not tested or assessed, the harms of NPS are not addressed Total harms may increase, as it may appear that NPS have the tacit approval of the state and are therefore seen as safe Harm reduction advice may be incomplete as products will not have been thoroughly tested Potential for anti-social behaviour around licensed retailers
Forensic Science	<ul style="list-style-type: none"> There may be reduced demand for forensic testing of products sold by licensed retailers if retailers complied with legislation 	<ul style="list-style-type: none"> Ongoing need to test and identify controlled and non-controlled NPS

Restricted Availability

Theme	Opportunities	Risks
Legal	<ul style="list-style-type: none"> • Easier to take action against those who are operating outside of the licensing regime • There may be a reduced burden on criminal justice system 	<ul style="list-style-type: none"> • NPS would still need to be controlled on a substance-by-substance basis • There are practical issues with implementation, particularly on how to reconcile the labelling provisions with existing alternative legislation for non-controlled NPS
Messaging and Communications	<ul style="list-style-type: none"> • Public concern over offline retail outlets may be reduced, as regulation can control the density, location and visibility of these outlets, and other retailers would be prohibited from selling NPS • Likely to be popular with those who support drug policy reform 	<ul style="list-style-type: none"> • Potentially controversial – unclear if public support this approach • NPS could be perceived as safe, despite the absence of any product testing • Illicit drugs would remain controlled, and these may be less harmful than non-controlled NPS • There may be local opposition to this approach which may require a further response from the Government
Costs	<ul style="list-style-type: none"> • The cost of licensing and compliance could be recovered through a fee to apply for licences • Revenue generating as tax and duty could be charged on NPS products 	<ul style="list-style-type: none"> • Increased healthcare costs if there are increases in short- and long-term health harms • Ongoing costs for enforcement against NPS sellers operating outside the licensing regime, and these may not be covered by the fee for licences

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