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Changes in the scope of control of substances

New psychoactive substances: overview of trends, challenges and legal approaches

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Summary

The unprecedented emergence in recent years of potentially dangerous new psychoactive substances (NPS) that are not under international control has led to their increased abuse, hospital emergency admissions and sometimes fatalities. These NPS, while often marketed as "legal" alternatives to substances under international control, may inadvertently pose a public health risk. The identification and detection of NPS form the basis of effective law enforcement responses and health interventions as part of a scientific evidence-based, balanced, comprehensive and integrated approach to drug policy that seeks both to reduce demand and to restrict supply in order to prevent abuse. This paper captures the key features and trends of the NPS problem since its emergence, including the challenges faced by several countries to identify and detect NPS. It highlights measures such as national legislative responses and international law enforcement cooperation initiatives implemented to address the issue and concludes with a summary of the remaining challenges posed by NPS.

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I. Introduction

A. New psychoactive substances — a threat to human health and well-being

1. The unprecedented emergence in recent years of potentially dangerous psychoactive substances that are not under international control has led to their increased abuse, hospital emergency admissions and sometimes fatalities. These new psychoactive substances (NPS), while often marketed as “legal” alternatives to substances under international control, may inadvertently pose a public health risk.

2. The harmful effects of NPS as described in reviews by the World Health Organization (WHO) Expert Committee on Drug Dependence and in other related literature include: tolerance, withdrawal symptoms and dependence-producing properties in the case of synthetic cannabinoids; high-frequency drug injection and the associated risk of transmission of blood-borne infectious diseases such as HIV, and emergency room admissions and fatalities due to the use of synthetic cathinones such as mephedrone; and overdoses due to the highly potent phenethylamine substances often sold as LSD.

3. The identification and detection of NPS form the basis of effective law enforcement responses and health interventions. This key issue is reflected in Commission on Narcotic Drugs resolution 57/9, entitled “Enhancing international cooperation in the identification and reporting of new psychoactive substances and incidents involving such substances”, which underscored the need to detect, analyse and identify new psychoactive substances as part of a scientific evidence-based, balanced, comprehensive and integrated approach to drug policy that seeks both to reduce demand and to restrict supply in order to prevent abuse. Unfortunately, forensic laboratory capacity in most countries is either lacking or not adequate to support the scientific evidence-based approach.

4. Four years after the Commission on Narcotic Drugs first expressed concerns regarding the emergence and associated dangers of NPS in its resolution 55/1, entitled “Promoting international cooperation in responding to the challenges posed by new psychoactive substances”, NPS continue to emerge on the market at a fast pace, while the understanding of their associated health and social harms remains limited.

5. This paper captures the key features and trends of the NPS problem, including the challenges faced by several countries to achieve the fundamental issue of identification and detection. It highlights measures such as legislative responses and international law enforcement cooperation initiatives implemented at the national and international level to address the issue and concludes with a summary of the remaining challenges posed by NPS.

B. Understanding the synthetic drugs problem

6. The 2009 *Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem* recognized systematic global monitoring as the key to understanding

the synthetic drugs problem. In response to the increased NPS threat, UNODC began to gradually incorporate NPS in its global synthetics monitoring analysis reporting and trends (Global SMART) programme. Set up in September 2008, the Global SMART programme had been helping targeted Member States to improve their capacity in monitoring synthetic drugs through the generation, management, analysis, reporting, and use of information on those types of drugs. In 2011 the Global SMART programme began raising awareness of the dangers of NPS and in March 2013 it presented its first global report entitled "*The challenge of new psychoactive substances*", which provided a consolidated analysis and a comprehensive overview of the nature and magnitude of the challenges associated with the NPS phenomenon.

7. Pursuant to Commission on Narcotic Drugs resolution 56/4, entitled "Enhancing international cooperation in the identification and reporting of new psychoactive substances", UNODC launched in June 2013 the first international monitoring system on NPS called the Early Warning Advisory (EWA). Since its inception, EWA has improved the understanding of the synthetic drugs market, particularly of NPS and has served as a knowledge hub and platform for sharing best practices including control measures, laboratory analysis and NPS legislation. EWA has also served countries as a resource for the identification and prioritization of candidate substances for scheduling notification as specified by the International Drug Control System.

8. EWA continues to work towards enhancing the ability of countries to anticipate NPS threats and to reduce public health risks through its early warnings, which is consistent with *Sustainable Development Goal 3* (Ensure healthy lives and promote well-being for all at all ages). The global monitoring of NPS in the last 3 years has shed light on the complexity of the problem, particularly its interplay with existing drug markets, and how countries respond at the national, regional and international levels.

II. Key features of new psychoactive substances

A. Threat to public health and safety

9. The risks and adverse effects to public health associated with NPS, including harm to young people, are a global concern in several regions of the world. The use of synthetic cannabinoids (e.g. JWH-018),[1] for instance, has been linked to fatal and non-fatal intoxications, instances of driving under the influence of those substances, as well as seizures, tachycardia and hypertension.[2] Many adverse effects have also been linked to synthetic cathinones. Mephedrone, for instance, has been associated with binge use (i.e. repeated use of the drug within a short period of time) while MDPV[3] has been associated with severe agitation, violent behaviour, tachycardia, psychosis, paranoia and anxiety. Fatal and non-fatal intoxications involving MDPV have also been reported. The danger associated with NPS use is accentuated by the

[1] JWH-018 is under international control since 2015.

[2] WHO Expert Committee on Drug Dependence: thirty-sixth report (Geneva, Switzerland, 16-20 June 2014).

[3] MDPV is under international control since 2015.

intentional mislabelling of products containing those substances and thus their unknown purity and composition.

10. The injection of synthetic drugs, including amphetamine-type stimulants (ATS) and NPS, has also been reported by several countries. People who inject ATS/NPS are reported to be at high risk of acquiring and transmitting HIV and other blood-borne diseases because their injection rate is higher and are thus more likely to share needles and other contaminated injecting paraphernalia and exhibit high-risk sexual behaviour.

B. Unprecedented rate of emergence of a global dimension

11. The emergence of NPS is a global phenomenon and all regions of the world have been affected by it, albeit, to different extents. By 2013, 348 NPS in 94 countries and territories from every region of the world had been reported to UNODC, with most substances having been identified between 2008 and 2013. By December 2015, over 643 NPS had been reported by 101 countries to UNODC, showing a stark and unprecedented increase in NPS emergence since 2008. New NPS continue to emerge every year at an average rate of one substance per week.

C. Transient nature of some new psychoactive substances

12. Even though more countries report a growing number of substances every year, some NPS are transient in nature. Many NPS have only been reported by a small number of countries in a given year and some seem to have disappeared completely from the market. However, some substances such as JWH-018 and mephedrone, which have been on the market since monitoring began in 2008 and which are now under international control, remain available on illicit drug markets.

D. Diversity

13. New psychoactive substances are very diverse in terms of their effects and chemistry and those identified to date mimic the effects of the six main groups of illicitly-used substances controlled under the international drug conventions, which are opioids (e.g. heroin and morphine), cannabinoid agonists (e.g. cannabis), psychostimulants (e.g. cocaine and amphetamine-type stimulants), classical hallucinogens (e.g. LSD and 2C-B), anaesthetic dissociatives (e.g. phencyclidine) and sedatives/hypnotics (e.g. diazepam). Synthetic cannabinoids, for instance, are sold as a “legal” herb-based alternative to cannabis, targeting the cannabis market, which is also the largest drug market.

E. Heterogeneity

14. Different patterns of NPS emergence have been observed across the different regions of the world, both in terms of the presence of NPS groups in specific regions and in the number of NPS reported by individual countries. Europe is the region that has reported the highest number of substances while ten countries that have reported the largest number of substances are spread

across three regions: Asia (Japan), Europe (Finland, Germany, Hungary, Russian Federation, Sweden, Turkey, United Kingdom of Great Britain and Northern Ireland) and North America (Canada and the United States of America). The Americas (excluding Canada and the United States) and East and South-East Asia have also reported significant numbers of NPS. In other regions, including Africa, Central America, the Near and Middle East and Central and South-West Asia, data on NPS emergence remain limited, making it very difficult to monitor and assess the impact of NPS in these regions.

F. New psychoactive substances are sold in mixtures

15. Seizure reports indicate that NPS are frequently sold in mixtures with other substances, which may or may not be known to the user. Furthermore, since limited or no scientific information is available on the effects that such combinations may have, users of those mixed substances could be exposed to considerable health risks. NPS products have been found to contain mixtures of NPS with controlled substances such as cocaine, MDMA and amphetamine or mixtures of different NPS within the same group (e.g. among synthetic cannabinoids) or across different NPS groups. In 2013, Europe reported more than 110 NPS products that combined up to 7 different NPS.

G. Detection and identification of new psychoactive substances

16. The detection and identification of NPS are critical to both supply reduction and health intervention strategies and to the collection of accurate data for effective policymaking. Unfortunately, relevant institutions in several countries face challenges to detect and identify NPS in both seized materials and in biological specimens from affected users.

17. Insufficient capacity to identify, analyse and report NPS is recognized as a factor in the low level of information received from some countries. Thirty out of 45 countries that provided information on legislation in the UNODC survey on NPS indicated that they experienced challenges in implementing legislation to control NPS. Of those 30 countries, 80 per cent reported that their law enforcement authorities (such as customs and police) face difficulties identifying controlled NPS.[4] Only nine per cent of the total countries surveyed reported that identification for law enforcement authorities was not a problem.

H. Market Resilience

18. The NPS market is resilient, adapting very quickly to changes introduced by legal controls and to substances forced out of the market due to their harmful effects. Of the 30 countries that experienced challenges implementing legislation to control NPS, 23 confirmed that NPS under national control were being replaced rapidly by new uncontrolled substances. Substances under national control in one country resurfaced in countries with weaker legal frameworks where NPS still

[4] 2014 UNODC survey on NPS, distributed to all Member States.

remain legal or on the Internet in websites that can only be accessed with anonymising software.

19. A good example of NPS market resilience involves substances belonging to the synthetic cannabinoids group. This group of substances evolves constantly to keep up with a market that is now more responsive to legislation. Chemical families with successive structural modifications evolve continuously to keep those substances in an ambiguous legal status. For instance, the emergence of the naphthoylindoles to which JWH-018 belongs, was quickly followed by the emergence of naphthoylindazoles (e.g. THJ-018) and more recently of indazole carboxamides (e.g. AKB-48).

I. The role of the Internet

20. The Internet plays an important role in the supply of NPS and regular mail shipments are recognized as one of the main distribution methods for those substances. The Internet is a challenging distribution channel because it is an easy, anonymous and low-risk way to supply NPS and it offers high rewards to suppliers and retailers. Internet websites participating in the trade/traffic of NPS may be based in countries different from those where NPS are manufactured and/or supplied to, and the disparity of laws in various countries makes it very challenging to find a common approach for the prosecution of violations. A further complication is the sale of products containing controlled NPS on the “darknet”, which can only be accessed with anonymizing software.

III. Measures taken

21. In resolution 57/9, entitled “Enhancing international cooperation in the identification and reporting of new psychoactive substances and incidents involving such substances”, the Commission on Narcotic Drugs recommended, inter alia, that “Member States exchange ideas, best practices and experiences in adopting effective responses at the national and regional levels to address the challenges posed by new psychoactive substances, such as through the use of early warning systems to identify potential threats, new and existing legislation, temporary restriction measures in response to harmful effects on public health, enforcement initiatives, and prevention, demand reduction and treatment strategies”.

22. While some progress has been made by Member States and the international community, significant efforts are still necessary to effectively address the NPS phenomenon. This section attempts to summarize some measures, implemented at national, regional and international levels to address the unique challenges posed by NPS.

A. Monitoring and Early Warning Systems

23. Monitoring is paramount to understanding the NPS market and its characteristics and it provides an evidence base to inform policies and responses to address the ongoing challenges posed by NPS. Many countries have adopted strategies to monitor NPS either by including them into their existing drug

monitoring systems (e.g. Australia,[5] Belgium,[6] Canada,[7] Chile,[8] Colombia,[9] Italy[10]) or by creating systems specifically designed for that purpose (e.g. the United Kingdom Forensic Early Warning System). In terms of regional monitoring systems, the European Monitoring Centre for Drugs and Drug Addiction's Early Warning Systems is one of a kind and an example of best practice in terms of regional cooperation in the use of early warnings to improve preparedness.

24. At the global level, NPS monitoring is carried out through the UNODC Early Warning Advisory (EWA) on NPS. Launched in 2013 and pursuant to Commission on Narcotic Drugs resolutions 55/1 (2012) and 56/4 (2013), UNODC EWA collects information on the global appearance of new substances from 101 countries and territories. To support Member States in the detection and identification of NPS, EWA offers information on NPS trends, national legislative responses, manuals for drug testing laboratories and technical information (e.g. analytical methodologies, reference documents, and mass spectra data). The UNODC Laboratory and Scientific Section administers EWA through the Global SMART programme. More information can be found at www.unodc.org/nps.

B. Prevention and risk communication

25. Effective risk communication is also key to preventing and controlling NPS. Some Member States have incorporated NPS in their drug prevention awareness programmes, in some cases using the Internet to disseminate information and raise awareness on NPS risks and related services. Despite these efforts, more progress is needed, particularly in: (a) raising public awareness of the risks of NPS from a clear legal stance, (b) improving education and sensitization of first respondents, and (c) devising strategies to reduce the harmful consumption of NPS. From an international perspective, information on NPS risk assessments is made available on an ongoing basis on the UNODC EWA list of announcements. Published literature on toxicology, pharmacology and use of NPS is also accessible through EWA.

C. Legislative responses

26. The unprecedented number of NPS and their rate of emergence present a challenge to drug control systems. Putting a potentially harmful substance under legal control may be a lengthy process that often requires evidence-gathering, a scientific review of harms and consultations. This means that a time lag is created from when an NPS comes into the market to when legal control is implemented. NPS manufacturers often exploit this inevitable time lag by developing and marketing alternative substances to circumvent established controls.

27. Many Member States and the international community, in an effort to protect public health, have explored a wide range of legislative responses to address the

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[5] The Ecstasy and Related Drugs Reporting System (EDRS).
[6] Belgian Early Warning System on Drugs.
[7] Canadian Centre on Drug Abuse.
[8] Chilean Drug Observatory.
[9] Colombian Drug Observatory.
[10] Italian Early Warning System.

dynamics of the NPS market, particularly the rapid emergence and attempts by manufacturers to circumvent legislation; the diversity of the problem; and paucity of data to enable full evaluation of harm.

1. The international control system

Discretionary provisional controls

28. The international conventions, in situations of urgency, allow for the establishment of temporary control measures to prevent widespread abuse before bringing a substance under international control. In 2014, Member States implemented, for the first time, discretionary provisional control measures, as prescribed under article 2 (3) of the 1971 Convention.

29. Reports on the use of mephedrone, a synthetic cathinone structurally similar to amphetamines and whose effects are reported to be similar to controlled drugs such as amphetamines, MDMA and cocaine, emerged in 2007. The substance rapidly became widespread, with 44 countries and territories reporting its emergence by December 2013 and over 40 countries adopting national controls on this substance. The health harms posed by mephedrone and its persistence on the drug market despite national controls, led the United Kingdom, in January 2014, to submit a notification to the Secretary-General to initiate the review of the scope of the international control of mephedrone according to the provisions of article 2 of the 1971 Convention.

30. Since a scheduling decision could not be made without prior assessment and recommendation on the scope of control by WHO, the notification submitted by the United Kingdom included a proposal for discretionary provisional control measures on mephedrone. In accordance with the provisions of the 1971 Convention, provisional control measures are discretionary and therefore a Party is not bound to impose such measures, nor is it held accountable for the reasons for which it may refuse to apply them. Following this period of provisional control, the Commission on Narcotic Drugs in 2015 decided to place mephedrone in Schedule II of the 1971 Convention upon recommendation by WHO.

Prioritization of new psychoactive substances

31. Not all NPS that have emerged on the global market satisfy the criteria for harm required for international control. A wide range of legislative responses has been adopted at the national level to control NPS that are considered a health threat (see annex). Drawing on these national controls and bearing in mind the diversity of NPS on the global market, the 2014 UNODC-WHO Expert Consultation on NPS recognized the need to prioritize the international control of NPS that are *more persistent*, *prevalent* and *harmful*. The Expert Consultation concluded that a phased approach to NPS prioritization was required, with the two main criteria for consideration being evidence of harm (or potential harm) of a substance, and the prevalence (or proxies for prevalence) of its use.

32. Efforts to prioritize NPS that require an international response have succeeded in keeping the international drug control system focused on those that are more persistent, prevalent and harmful. The prioritization process consists of various stakeholders including the International Narcotics Control Board (INCB), UNODC and the European Monitoring Centre for Drugs and Drug Addiction, providing

information to assist WHO in the selection of substances for review and their risk assessment. In 2015, for instance, 9 out of the 643 reported NPS were prioritized by the WHO Expert Committee on Drug Dependence for consideration at its 37th Meeting in November 2015.[11]

33. Notwithstanding the initial success in prioritizing substances for international control, the creation of a comprehensive global evidence base for prioritization, as a foundation for the international control of harmful NPS, continues to be hampered by difficulties in the detection and identification of NPS by some Member States. The capacity of forensic laboratories in both health care and law enforcement is key to the compliance of governments with the provisions of the international drug control treaties and thus needs to be strengthened. Various aspects of drug control depend on the ability of forensic laboratories to identify NPS, including the development of measures that individual governments can take to combat drug trafficking and abuse as well as governments' fulfilment of their reporting obligations under the international drug control treaties.

2. National legislative responses

34. The diversity of NPS that has emerged at the global level is reflected in the variety of legal approaches adopted by Member States to control NPS at the national level. The annex provides a summary of legislative responses put in place by countries to address the NPS issue.

35. In general, countries affected by a limited number of NPS often control NPS on a substance-by-substance basis (i.e. individual listing). Fifty-four (54) out of 57 countries, on which information on legal responses is available on UNODC EWA, have added at least one NPS to the list of controlled substances at the national level. In some cases this has been carried out either through lengthy regular legislative processes or through rapid procedures and/or temporary controls. Temporary bans enable the introduction of time-limited controls on NPS to protect public health from potentially harmful substances until sufficient scientific evidence to inform permanent control decisions becomes available.

36. Countries affected by a high number of NPS have resorted to measures that go beyond placing individual substances under control, for example by applying analogue and/or generic controls. These enable the control of NPS that are chemically similar to a drug already controlled (*analogue control*) or of whole groups of NPS (*generic control*), without the need to refer to each individual substance in the legislation. In Europe and North America, where a significant variety of NPS has been reported, generic controls on NPS groups have been introduced in at least 13 countries.

37. Some Member States have resorted to the use of consumer protection laws and/or medicines legislation to control NPS. Fourteen countries in Asia, Europe, North America and Oceania have used either consumer protection laws and/or medicines legislation to protect public health and to reduce the supply of NPS by seizing stock and closing down retail outlets, at least temporarily. However, products containing NPS are often labelled as "not for human

[11] 37th WHO Expert Committee on Drug Dependence 16-20 November 2015, provisional agenda www.who.int/medicines/access/controlled-substances/37th_ECDD_Provisional_Agenda.pdf.

consumption" and sold as "research chemicals" to bypass existing consumer legislation. Forty-two per cent of the 45 countries that submitted responses to the 2014 UNODC survey on NPS indicated that the intentional mislabelling of products/packages containing NPS facilitated the bypass of NPS legislation.

38. Given the particular characteristics of NPS, some countries have adopted NPS-specific legislation to tackle the problem. These legislative approaches range from a general prohibition on the distribution of NPS to pre-market approval regulatory regimes and controls on psychoactive substances which are intended for human consumption and capable of producing a psychoactive effect.

D. Enhancing capacity to detect and identify new psychoactive substances

39. UNODC, through its laboratory and forensic services programme continues to assist Member States to develop and strengthen their capacity to detect and identify NPS by developing and disseminating recommended laboratory methods of analysis of recently controlled substances; providing chemical reference standards to aid laboratory analysis of NPS in seized materials and biological specimens; updating key knowledge products such as the *Multilingual Dictionaries on Drugs and Precursors under international control* and the *Terminology and Information of Drugs*.

40. The UNODC International Collaborative Exercises (ICE) programme whose implementation allows laboratories, from both developing and developed countries, to continuously monitor their performance in drug analysis on a truly global scale, has been expanded to cover NPS. With support currently provided to over 200 national drug testing laboratories in over 63 countries, ICE continues to be a critical source of information on emerging drugs for UNODC EWA.

41. The UNODC Scientific and Forensic Services programme provides technical capacity to support law enforcement activities related to synthetic drugs in different regions. For instance, in East and South-East Asia and the Pacific, technical support was provided for the development of standard operating procedures for multilateral cooperation; in the Gulf region and in South Asia, law enforcement authorities were trained on UNODC EWA; while in West Africa, a forensic training workshop on drugs and precursors was implemented in collaboration with Global SMART, the Container Control programme, the Airport Communication Programme and the West African Coast Initiative.

42. While some progress has been made on a global scale in the detection and identification of NPS, in many countries this continues to be a major challenge in terms of monitoring and reporting, informed treatment interventions and in the implementation of scheduling decisions.

E. Supply reduction

43. Divergent approaches in national legislation give way to loopholes and thus the proliferation of NPS. The pattern of distribution of NPS is that substances, normally not under national control in their country of origin, are ordered/purchased

by foreign clients or drug traffickers and exported abroad, mostly by mail. NPS are further distributed to users usually through friends, dealers and head shops but some users also purchase NPS directly from Internet websites. Over 50 per cent of respondents to the 2014 UNODC survey on NPS recognized that the trade/traffic of NPS through the Internet and postal networks makes it difficult to enforce NPS legislation. Regional and international cooperation in the identification and reporting of NPS, of incidents involving such substances, and on efforts against the illicit manufacture, trafficking and consumption of NPS, is therefore fundamental for disrupting the supply.

1. International cooperation

44. As part of its mandate to support governments in preventing the diversion of drug precursors and other substances used for the illicit manufacture of drugs, the INCB *Project ION* (International Operations on NPS) promotes international cooperation among law enforcement agencies to prevent and combat the illicit traffic of NPS. Project ION's Incident Communication System (IONICS) facilitates intelligence-sharing (e.g. information on suspicious shipments of, trafficking in, and manufacture or production of NPS) among law enforcement agencies and provides support to operational responses on NPS carried out by Member States.

45. With the bulk of NPS importations taking place via mail and fast parcel services, the *Customs Enforcement Network* (CEN) of the World Customs Organization is a platform that aims to facilitate NPS-related operations among its Member States and provide a secure messaging system for cross-border operations. This platform represents a central global depositary for enforcement-related information. The CEN database features more than 3,800 cases of NPS seizures reported between January 2012 and July 2013. In Asia and the Pacific, information on NPS seizures is shared through a platform managed by the World Customs Organization Regional Intelligence Liaison Office and fed from data submitted by customs offices in those regions.

2. Efforts by perceived source/transit countries

46. China and India are frequently perceived as major manufacturers of NPS while Europe is perceived as a trans-shipment region of NPS. However, a number of European countries, such as the Czech Republic, Hungary, the Netherlands, Portugal, Spain, Ukraine and the United Kingdom, have also been identified as potential sources of NPS.[12] What is not yet clear is whether other activities, such as refining, tabletting, cutting, packaging and manufacturing, are also taking place in those European countries.

47. Some Member States perceived as source countries have strengthened their legal frameworks to control NPS. For instance, China carried out a multi-agency study on NPS and initiated temporary control mechanisms in 2012. In 2015, the country placed over 110 NPS under national control in a single exercise. In India, only a limited number of NPS has been placed under control. In the United Kingdom, which is perceived as a transit hub, a comprehensive ban on the distribution of any psychoactive substance became law earlier this year and is

[12] Sources are reported by the respondents to the UNODC 2012 questionnaire on NPS and have not been validated scientifically as manufacturing/production sites.

expected to enter into force in April 2016. Information on the legislation adopted by European countries perceived as potential sources of NPS can be accessed through UNODC EWA.

IV. Remaining challenges

A. Risk communication

48. While some Member States have undertaken efforts to raise awareness regarding the potential risks associated with the use of NPS, awareness-raising campaigns have not been conducted on a systematic basis; this means that awareness-raising does not exist in many countries or is lacking in entire regions. Early warning systems offer an opportunity that can be explored for a continued and expanded coverage of awareness-raising and risk communication at the national, regional and international levels, but those awareness campaigns need to be adequately resourced, expanded and promoted if they are to meet their full potential and adequately protect children and young people from the harms associated with the illicit sale and purchase of NPS.

B. Demand reduction

49. While progress has been made in providing a basic understanding on the emergence, trends and composition of NPS, prevalence data remain limited to specific user groups and so far there are no global estimates on the prevalence of NPS among the general population. Detection and identification of NPS are critical to health intervention strategies and to the collection of accurate data for effective policymaking. This means that the capacity of forensic laboratories to detect and identify NPS is a precondition for the development of comprehensive and balanced prevention and treatment models and thus paramount to countering the harmful effects of NPS. Existing NPS platforms can be used to share information and expertise on national health-related experiences, including for use at emergency departments in hospitals.

C. Prioritization and legal controls

50. There is a need to strengthen the capacity of WHO, UNODC, INCB and other relevant stakeholders, to continue building and expanding on the success of the prioritization process and to facilitate informed scheduling decisions by the Commission on Narcotic Drugs. Existing platforms such as UNODC EWA and INCB IONICS could be further expanded to disseminate early warnings and surveillance lists to improve information-sharing and international cooperation among Member States.

D. Supply reduction

51. Notwithstanding the efforts to improve the capacity of law enforcement authorities and forensic laboratories in the detection and identification of new

psychoactive substances, some Member States, especially in some regions of the world, continue to have insufficient capacity to identify and monitor NPS. Enhancing the capacity of those laboratories and improving cooperation among them, including through the use of existing UNODC reference standards and through participation in the UNODC ICE programme, are key preconditions for governments to implement proper drug control interventions and to comply with the reporting obligations of international drug control treaties.

Annex

Overview of legal approaches to control new psychoactive substances at the national level

A. Drug control legislation

1. Individual listing of substances

Following the model of the international drug control conventions, individual substances are controlled once their harm has been assessed. They are often divided into schedules/lists that classify them individually based on medical use, their relative abuse potential, and their likelihood of causing dependence when abused. Each schedule is subject to a graded system of control and restrictions. Examples of this approach to control NPS are the scheduling of BZP, TFMPP and mCPP in New Zealand, in 2008, and the control of mephedrone in Brazil, in 2011.[13]

Benefits and opportunities

- Controlled substances are specified individually.
- This approach seems to be sufficient in countries where the number of NPS identified is limited and where the spread of NPS on the drug market is not foreseeable in the near future.

Limitations

- Scientific and human experience data are required to assess the health risks associated with a substance before deciding on its scope of control in many drug control systems. In the case of some NPS, those data are often unavailable, making it very difficult to justify legal controls.
- The legislative process associated with placing new substances under drug control legislation is often lengthy, taking at least several months, and leaving a prolonged time lag between the time the dangerous NPS emerge on the market and the time controls are introduced, thus exposing users to health risks.

1.1. Temporary bans

Through temporary bans, administrative authorities can rapidly (in a matter of days or months), via statutory instruments, introduce controls similar to those that apply to the illicit manufacture or trafficking in drugs to NPS (individually or as a group of compounds) that pose an “immediate risk” or are considered to be “dangerous” and a threat to public health, while health issues are assessed by the competent authority and a final decision on control is taken. Temporary controls are limited in time (usually from 6 months to 1-2 years). Drugs controlled under temporary legislation are often subject to reduced or no penalties for personal use quantities, with manufacture, importation, exportation and supply being the main focus of control.

[13] BZP and mephedrone have been under international control since 2015.

Examples of the use of temporary bans to control NPS can be found in the legislation of Hungary, Italy, Latvia, New Zealand, the Republic of Korea, Singapore, the United Kingdom of Great Britain and Northern Ireland and the United States of America.

Benefits and opportunities

- Temporary bans enable a quicker response to control the supply of potentially harmful NPS when there is little knowledge/evidence of their harms while health issues are fully assessed by independent experts.

Limitations

- Temporary controls are limited in time, and in many cases the time is insufficient for the evidence of NPS harm to become available to justify permanent controls.

1.2. Rapid procedures

Like temporary bans, rapid procedures are not per se legislation to control NPS, but a system to speed up, in cases of urgency, the standard legislative procedure required to place new substances under permanent control. Thus, in order to accelerate the process, the omission of one or more of the standard legislative steps or the reduction of procedural times to consider the decision by the parliamentary chambers and/or by the President, is permitted.

Rapid procedures can be differentiated from temporary bans based on two main criteria. The first criterion is that, compared to the standard legislative process, in the case of rapid procedures the required level of final approval of the legal text is maintained, but the duration of the consultations is shortened whereas in the case of temporary bans, the level of final approval of the legal text is lowered, e.g. from presidential/royal assent to Ministerial approval. The second criterion is that the bans of substances taken under rapid procedures are permanent and not limited in time, unlike in the case of temporary bans. Countries that have used rapid procedures to control the supply of NPS include Luxembourg, Norway, Poland, Slovakia and Sweden.

Benefits and opportunities

- Accelerated legislative or regulatory processes to control NPS provide a rapid response to counter an imminent health threat posed by certain known harmful substances (e.g. mephedrone or NBOMe compounds).
- Substances controlled under rapid procedures are subject to permanent controls.

Limitations

- Health Advisory Councils/Boards continue to face serious difficulties in advising the legislative process due to data paucity on the health harms associated with specific substances, which is a common feature with many NPS.

1.3. Generic controls

Generic controls complement the list of individually controlled substances by prohibiting at once groups of substances (that include large numbers of individual NPS) encountered and/or to anticipate controls on new substances that may arise. Generic controls target the core molecular structure, which does not itself have to be psychoactive, with legislation specifying particular variations of the structure (particularly substituent groups in specified positions in the molecule) that could fall under control. Substances under the generic definition show a defined structural similarity to a known illicit drug or parent compound described in the legislation even though the names of those substances are not individually mentioned in the legislation.

The generic language goes beyond the terms isomers, esters, ethers and salts and refers, for instance, to specific subgroups of NPS such as naphthoylindoles and benzoylindoles indicating the replacements and substitutions that fall under control. For instance, a variety of naphthoylindoles that could be produced by replacement of the pentyl substituent on the indole ring of JWH-018 are covered by the generic legislation adopted so far in several countries.

Countries and territories that have used this approach to control one or more groups of NPS include Austria, Denmark, France, Hungary, Hong Kong (China), Ireland, Israel, Japan, Lithuania, Norway, the Russian Federation, Switzerland, the United Arab Emirates, the United Kingdom and the United States.

Benefits and opportunities

- In countries affected by the proliferation of a large number of NPS, this approach has allowed control of large groups of substances present on the market without needing to name them individually, and has also enabled the introduction of “future proof” legislation, to be one step ahead of drug manufacturers and controlling substances that may appear but may have not yet emerged on the market.
- The generic approach seems feasible for small and simple groups of NPS because the number of potential compounds is limited.

Limitations

- Generic controls may be questioned in view of constitutional principles, particularly those related to the fact that individuals should not be convicted of a crime without having had knowledge that a particular substance was banned.
- Controlling substances with a much larger skeleton is challenging due to the possibilities of diversification. For instance, in the case of synthetic cannabinoids, new variations, seemingly designed to circumvent legislation, appear regularly, quickly outdating a generic legislation.
- When introducing generic controls, it should be considered that not every modification on parts of the structure of a controlled compound will necessarily ensure that the compound remains pharmacologically active and should be controlled.

- In the absence of rigorous definitions of cluster of compounds and/or in the inclusion of specific exceptions on medicines and substances used for research, substances which are not intended to be controlled because of legitimate industrial, scientific and medical use, may unintentionally fall under generic controls.
- Enforcement of generic legislation could be challenging as in many cases law enforcement authorities face difficulties in identifying the substances controlled under a generic approach.

1.4. Analogue controls

With analogue legislation, invoking the concept of "chemical similarity" to a controlled drug allows for the control of substances that are not specifically mentioned in the legislation. Thus, a substance which is both structurally similar to and has a similar or greater effect on the central nervous system as an already controlled substance, is deemed to be a controlled substance analogue and is as such under control. Analogue legislation operates on a substance-by-substance basis and, unlike generic controls, addresses more general aspects of similarity in chemical structure to a "parent" compound.

The definition of what is considered an analogue, the interpretation and applicability of the concept and the penalties associated with the infringement of analogue legislation vary from country to country. In addition to the requirement of chemical similarity, criteria such as pharmacological similarity and/or evidence that the substance is sold for human consumption are used in some countries to delineate more clearly the definition of analogue substances.

An example of the use of analogue legislation to control NPS is provided by Canadian legislation. In Canada, methylone has been considered to be an analogue of amphetamine, which is included in Schedule I of the Controlled Drugs and Substances Act (CDSA). Synthetic cannabinoids, such as JWH-018, are considered to be similar synthetic preparations of cannabis and therefore fall under the controls of Schedule II of CDSA.

Benefits and opportunities

- Analogue controls may eliminate the need to continually update the schedules of controlled substances as not every substance falling under control via analogue legislation would need to be individually named in the legislation.

Limitations

- Analogue controls may have unintended negative consequences on legitimate manufacturers and suppliers of substances for medical and/or research purposes, because they may not have the means to verify whether a substance that they are manufacturing or selling is deemed analogous to a controlled substance and may thus run the risk of prosecution.
- Analogue legislation operates on a substance-by-substance basis, which implies that an assessment of the chemical structure and/or pharmacological similarity of an NPS against that of existing controlled substances needs to be performed for each individual substance.

- The requirement of pharmacological similarity to prove analogy may be very challenging for a number of NPS that have not been studied and thus lack pharmacological information.
- The lack of a recognized scientific method to determine the "substantial similarity" of two substances makes determining whether a substance is deemed to be a controlled substance analogue very complex and resource-intensive for law enforcement and prosecuting authorities.

1.5. Neurochemical approach

Through this approach substances are controlled based on the effect they have on the brain rather than through the listing of specific substances or the use of class definitions. This approach has been used so far only to control synthetic cannabinoids but its future application to other NPS groups cannot be excluded.

In 2012, the United States introduced this approach to control NPS, in particular "cannabimimetic agents". Under the "Synthetic Drug Abuse Prevention Act 2012" cannabimimetic agents are defined as "any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays" within defined structural classes. The definition includes a group of substances with possible chemical variations but which have a specific effect through binding to the CB1 receptor. According to the Act, any preparation "... which contains any quantity of cannabimimetic agents, or which contains their salts, isomers and salts of isomers …" is placed under Schedule I, which is the schedule with the strictest controls.

Benefits and opportunities

- This approach could theoretically eliminate the need for continually updating the schedules of controlled substances every time a new synthetic cannabinoid is made or introduced into the market.
- There are relatively simple tests to determine the psychoactive effect.
- This approach provides clearer definitions than analogue controls.

Limitations

- The neurochemical approach may have unintended negative consequences on legitimate manufacturers and suppliers of substances for medical and/or research purposes, because they may not have the means to verify whether a substance that they are manufacturing or selling falls under the scope of the legislation, by having a specific effect through binding to the CB1 receptor, and thus may run the risk of prosecution.
- According to United States legislation, proof that the substance/chemical meets the structural criteria, as described, and that it satisfies the neurochemical definition are needed, but there is uncertainty in terms of what proof would be required to obtain a conviction under the "Synthetic Drug Abuse Prevention Act 2012".
- As the public may not easily understand this approach, a clear message to explain the approach is needed.

B. Other systems

1. Medicines Acts

Medicines legislation has been used to tackle or reduce the open availability of NPS. Classifying NPS as “medical products” means that they could be subject to licensing for their importation, marketing and distribution. However, the definition of “medical product” varies from country to country, as the interpretation and application of medicines law to control NPS.

Countries that have used medicines legislation as an initial response to the harms posed by NPS include eight European countries, including Austria, Finland, the Netherlands and the United Kingdom. In 2009, Austria used its Pharmaceutical Law to tackle the supply of a number of synthetic cannabinoids, while in 2007, the United Kingdom used medicines legislation to control benzylpiperazine (BZP).

Limitations

- In a recent ruling the European Court of Justice decided that the application of medicines laws to NPS was not appropriate because NPS fall outside the definition of medicinal products under the Common European Union law.
- Penalties applicable to the infringement of medicines legislation are usually less severe than those prescribed under drug control legislation.

2. Consumer protection laws

In the absence of specific regulations on NPS, consumer protection laws have been used to react quickly to reduce the open availability and sale of NPS, in order to protect public health. Some countries have targeted psychoactive products in general (see below the “general prohibition on the distribution of NPS”) while others have been directed to individual substances.

Consumer protection laws allow the introduction of age restrictions on sales, the obligation to indicate content, dosage and side effects, as well as the introduction of controls on packaging and marketing of products. Legislation breaches are usually sanctioned with civil and/or criminal sanctions.

Examples of using consumer protection laws to control NPS are provided by Italy, which is also the first country to use this type of legislation to control NPS. In 2010, several cases of acute intoxications following the ingestion of synthetic cannabinoids were reported to the Italian Early Warning System. Regulations on clear and accurate labelling of foods and goods for sale were used to confiscate synthetic cannabinoid products sold as “n-Joy” and “spice” because they were not labelled in the national language. While collecting information related to the danger to public health of the substances JWH-018 and JWH-073 and the completion of the procedure for their possible inclusion in the list of controlled substances, the Italian Ministry of Health in April 2010 prohibited the manufacture, import, marketing, trade, including sale via the Internet, and use of the products called “n-Joy” and “spice” and ordered their withdrawal from the market. In June 2010 these two synthetic cannabinoids were placed under permanent control.

Benefits and opportunities

- Initially used to tackle the sale of NPS that were frequently marketed as bath salts, plant food or other non-psychoactive substances and labelled as “not for human consumption”. Consumer protection laws cover the use of misleading description of consumer goods and services, and sanctions unfair commercial practices.

Limitations

- NPS suppliers often label their products as “not for human consumption” to bypass consumer protection laws.
- Many NPS are supplied through the Internet, which hinders the enforcement of consumer protection laws since websites are often based in countries different from the countries of distribution.
- Consumer protection laws require that products containing NPS provide safety information on dosage. This can be difficult to achieve in the case of NPS because the active dose for some of them is very low, knowledge of NPS potency remains limited, and NPS products are available in unrestricted quantities.

3. Specific new psychoactive substance legislation

Specific NPS legislation has been adopted in some countries to reduce supply but the legislative approach employed varies from country to country. In general terms, this NPS legislation differs from drug control legislation in that it does not criminalize drug use or possession of drugs for personal use as it focuses on preventing the manufacture and circulation of NPS, provided that they are destined for use for their psychoactive effects.

The use of specific NPS legislation in some countries has been preceded by the use of other types of legislation that had aimed to regulate specific NPS of concern. For instance, in Austria, specific NPS legislation was issued in 2011 (in force since 2012), after the country attempted to tackle NPS by using medicines legislation in 2009 and generic legislation in 2011. The new NPS-specific legislation granted powers to the Ministry of Health to designate individual or groups of NPS through a regulation for the purpose of control. Customs authorities were granted powers to seize NPS and the law also criminalized the manufacture, import, export and supply of NPS.

Countries that adopted specific NPS legislation include Austria (Federal Act on the Protection against health hazards in connection with new psychoactive substances), Ireland (Criminal Justice Psychoactive Substances Act of 2010), Romania (Law 194/2011 requires a specific permit to sell any product likely to provoke psychoactive effects similar to those caused by substances controlled under drug laws), and New Zealand (Psychoactive Substances Act).

Benefits and opportunities

- Possession of NPS for personal use is often not punishable under specific NPS legislation.

- Compared with drug control legislation, the process behind updating the list of controlled substances under specific NPS legislation is often more flexible, expeditious and simple.

Limitations

- Proving that NPS are destined for use for their psychoactive effects may be challenging for prosecutorial purposes, as many of the products containing NPS are labelled as “not for human consumption” or “research chemicals”.

4. General prohibition on the distribution of new psychoactive substances

This legislation establishes offenses related to the sale, import, export or advertisement of unregulated substances that are not specifically controlled under existing legislation or listed as a specific exception. These offences are sanctioned with imprisonment and/or administrative fines but there are no offences or punishment for possession for personal use of these substances.

This approach has been used in Ireland, Poland and Romania. In 2010, Ireland used this type of legislation to control the proliferation of retail outlets selling NPS, commonly known as “head shops”. In 2010, Poland amended its legislation to prohibit the placing on the market of “substitute drugs”, which was sanctioned with financial penalties. In 2011, Romania passed a law on counteracting operations with products suspected of having psychoactive effects, other than those stipulated in the regulations in force. The law prohibited operations (manufacture, production, processing, synthesis, extraction, distribution, offering for sale, transportation, etc.) with “substitutes” that were suspected or that could have been foreseen as having psychoactive effects, without an authorization, and prescribed prison sentences up to 5 years for the violation of this prohibition.

In 2016, the United Kingdom passed “the Psychoactive Substances Act” (to come into force on 6 April 2016), which makes it an offence to produce, supply, offer to supply, possess with intent to supply, possess on custodial premises, import or export psychoactive substances (i.e. any substance intended for human consumption that is capable of producing a psychoactive effect). The maximum sentence prescribed for this conduct is 7 years’ imprisonment. In addition to imprisonment, the Act includes provision for civil sanctions, including prohibition notices, premises notices, prohibition orders and premises orders (breach of the two orders will be a criminal offence), to enable the police and local authorities to adopt a graded response to the supply of psychoactive substances in appropriate cases.

Benefits and opportunities

- Tackles or reduces the open availability and sale of NPS as a whole without requiring NPS to be named individually. It has been useful to reduce the sale of NPS in head shops.
- Products can be withdrawn from the market for a certain period of time to assess their safety and whether there is reasonable suspicion that those products pose a threat to human health.

- If the safety requirements set by the law are fulfilled, it provides a "pre-authorization" risk assessment procedure that could result in an authorization to sell NPS.

Limitations

- Closure of head shops may redirect the supply of NPS to Internet or "darknet" websites or to organized criminal groups and street dealers.
- The pre-authorization risk assessment process must be completed for each individual NPS, but so far there is no evidence to support that this procedure is used.
- The enforceability of this type of legislation may be contested in Court, as the definition of "psychoactivity" remains unclear. Some legislations require that "psychoactive" effects be "significant" but it is unclear what this means.
- Suppliers and vendors can be prosecuted only if there is indication (e.g. product labelling, website information, verbal communication) that the accused knew or should have known that the substance was psychoactive and that it was being acquired or supplied for human consumption. The burden of proof rests on the prosecution to demonstrate that the compound is psychoactive beyond a reasonable doubt. This is a very challenging task for prosecutors since there is little or no information on the pharmacological activity of some compounds.

5. Full regulatory approach — pre-market approval regulatory regime

This legislation regulates the availability of psychoactive substances to protect the health of, and minimize harm to, individuals who use psychoactive substances. The importation, manufacture and supply of NPS is restricted to those NPS products shown with clinical trial data to pose a "low risk" of harm. Alcohol, tobacco, medicines and substances already controlled under drug control legislation are exempted from this regulatory approach. The decision on whether to approve a product or not would be made by an advisory committee and a regulatory authority who would evaluate the scientific evidence on a substance-by-substance basis.

A breach of the regulations would result in the suspension or withdrawal of the licence, and/or other administrative and criminal penalties.

New Zealand is the only country to pass legislation that introduces a pre-market approval regime for NPS in which manufacturers need to prove the low risk of harm of substances prior to their legal manufacture and sale. This legislation was passed in 2013 and amended in 2014 to ban the use of animal testing data in support of product approvals.

Benefits and opportunities

- A pre-market approval regulatory regime for NPS allows the introduction of retail restrictions on age, place of sale, advertising, labelling and packaging and the withdrawal of the most harmful NPS from legal sale.
- It can help reduce the number of NPS retail outlets and the number of legally available NPS products.

- Manufacturers are required to obtain approval from a regulator to legally manufacture and sell products containing NPS, providing scientific evidence that the products carry a low risk of harm. The financial costs of testing NPS products to prove their safety in advance of sale are borne by manufacturers.
- This system enables the display of health warnings and record-keeping and thus facilitates the monitoring of use and harm of NPS and the rapid withdrawal of harmful NPS from the market.

Limitations

- The paucity of data on the pharmacology and toxicology of NPS makes it very difficult to assess the risks posed by these substances.
- The approval time of products containing NPS is long and costly.
- It is not known how the pre-market approval regime would work, in particular the testing process, since the New Zealand legislation remains in a transitional phase.