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Implementation of the International Drug Control Treaties: Changes in the scope of control of substances

Expert Consultation on New Psychoactive Substances Vienna, 3-5 September 2013

Report by LSS/RAB/DPA/UNODC

Summary

The International Expert Consultation on New Psychoactive Substances, held in Vienna from 3 to 5 September 2013, set the scene for interactive discussions on possible international responses to the problem of new psychoactive substances. Within the scope of five plenary sessions, the consultation considered the World Health Organization's risk assessment process and related challenges, a historical review of the provisions under the international drug control treaties, changes in the scope of the control of substances, and monitoring the implementation of, and promoting compliance with, the provisions of the conventions by the Parties. National, regional and international approaches in monitoring of new psychoactive substances were considered, in addition to national legal responses to new psychoactive substances, in support of the international drug control system. The expert consultation further examined the efforts by relevant international organizations to counteract the threat of new psychoactive substances and proposed possible options for response.

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Contents

The terms used in this report are defined as follows:

ICE: International Collaborative Exercises are an important part of the UNODC International Quality Assurance Programme (IQAP). Participation in such exercises, inter-laboratory comparisons or proficiency tests is one of the essential elements for implementation of quality management systems. The UNODC ICE programme allows drug testing laboratories from both developing and developed countries to continuously monitor their performance on a global scale.[1]

NPS: New psychoactive substances are substances of abuse, either in a pure form or in a preparation that are neither controlled by the 1961 Single Convention on Narcotic Drugs nor by the 1971 Convention on Psychotropic Substances, but which may pose a public health threat. In this context, the term "new" does not necessarily refer to new inventions but to substances that have recently become available in specific markets. In general, NPS is an umbrella term for unregulated (new) psychoactive substances or products intended to mimic the effects of controlled drugs.[2]

UNODC EWA: The UNODC Early Warning Advisory (EWA) was launched in June 2013 as a response to the emergence of NPS at the global level. The EWA aims to monitor, analyse and report trends on NPS, as a basis for effective evidence-based policy responses. It also serves a repository for information/data on these substances and a platform for providing technical assistance to Member States.

[1] www.unodc.org/documents/scientific/ICE_2010_2_and_2011_1_overview.pdf.

[2] World Drug Report 2013, available online: www.unodc.org/unodc/secured/wdr/wdr2013/World_Drug_Report_2013.pdf.

I. Executive summary

1. The International Expert Consultation on New Psychoactive Substances (NPS) was convened pursuant to Commission on Narcotic Drugs resolution 55/1 of 2012 entitled "Promoting international cooperation in responding to the challenges posed by new psychoactive substances," which requested UNODC, subject to the availability of extrabudgetary resources, to exchange information on NPS, where appropriate, with relevant international organizations and global and regional cooperation frameworks including the International Narcotics Control Board (INCB), the World Health Organization (WHO), the International Criminal Police Organization (INTERPOL) and the World Customs Organization (WCO). The consultation, a closed meeting held in Vienna from 3-5 September 2013, brought together more than 60 participants from international and regional organizations as well as subject-matter experts from national drug control agencies, health departments and law enforcement agencies of selected countries.

2. The Deputy Executive Director of UNODC and Director, Division for Policy Analysis and Public Affairs opened the consultation. The agenda was outlined by the Chief of the UNODC Laboratory and Scientific Section. Within the scope of five plenary sessions, the Expert Consultation was conducted through presentations and question-and-answer sessions aimed at discussing ways of moving forward effectively within the context of the existing drug control conventions.

3. Based on the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol (1961 Convention) and the 1971 Convention on Psychotropic Substances (1971 Convention), WHO's risk assessment process and related challenges, as well as WHO's strategy for assessing the risks of NPS were presented. A historical review of the provisions for changes in the scope of control under the international drug control conventions was outlined, and information was shared on the process of notification, risk assessment and potential control measures, including the possibility of provisional control. Experts were briefed on monitoring of the implementation of, and promoting compliance with, the provisions of the conventions by State Parties.

4. The specific issue of NPS monitoring was addressed, taking into consideration national, regional and international approaches. At the national level, experts from Colombia and Sweden shared experiences of their respective early warning systems. In terms of regional efforts to monitor NPS, the meeting provided insights on activities by WCO's Regional Liaison Offices operating in Asia and Pacific and in Eastern and Central Europe, and of the European Early Warning system. At the international level, UNODC reported on the development of its Early Warning Advisory on new psychoactive substances.

5. An overview of analogue and generic legislation, and temporary control orders in controlling NPS, was provided by experts from Japan, the United Kingdom of Great Britain and Northern Ireland and the United States of America. National responses to NPS in selected countries as well as efforts to address the NPS challenge by perceived source countries were provided by experts from Canada, China, India, New Zealand and the Russian Federation. Efforts of international organizations, such as INCB, INTERPOL, WCO and WHO to counteract the threat of NPS were also presented.

6. Experts considered potential options for response to the problem of NPS at the international level. The possibility for greater utilization of the provisions enshrined in the international drug control conventions was identified. A demand for more efficiency and timeliness of the process from initiation/notification to recommendation of control measures was identified, including the prioritization of substances for purposes of control. The consultation noted the (pointed to) resource limitations with regard to the risk assessment of NPS. Experts concluded that the detection and identification of NPS required enhancing the capacities of forensic laboratories.

7. Data collection and sharing were identified as significant challenges. The need for standardization of terminology, avoidance of duplication of efforts, addressing disparities in national laboratory capacities, defining minimum criteria for, or guidance on, the development of national early warning systems was also outlined. Experts noted the necessity for enhanced cooperation between various monitoring systems in data collection and sharing. The scope of information disclosure when issuing early warnings was identified as a key issue in such cooperation.

8. With regard to supply reduction activities, experts identified intelligence-led law enforcement activities and related inter-agency collaboration as a significant part of the response to the NPS challenge. The Internet was identified as a complex distribution channel of NPS and a necessary target for law enforcement intervention. Prevention and demand reduction activities were also recognized as necessary components in a balanced approach to addressing the NPS issue.

II. Introduction and background

9. Within the last decade, the use of new psychoactive substances has rapidly increased, in contrast to the prevalence rates for the use of internationally controlled drugs, which generally seem to have stabilized over the same period. The continued growth of the dynamic NPS market has evolved into a significant policy challenge for Member States and is currently a major international concern.

10. The UNODC, under its Global Synthetics Monitoring: Analyses, Reporting and Trends (SMART) Programme published the first global assessment of NPS entitled "*The challenge of new psychoactive substances*"[3] in March 2013. The number of NPS reported by Member States to UNODC rose from 166 at the end of 2009 to 251 by mid-2012, and to more than 350 by August 2013,[4] outnumbering the total number of psychoactive substances currently controlled under the 1961 Convention and the 1971 Convention. While 70 countries reported the emergence of NPS by mid-2012, this number increased to nearly 90 countries by August 2013.[5] Most of the reporting countries are located in Europe, followed by Asia and the Americas.

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[3] "*The challenge of new psychoactive substances*," available online: www.unodc.org/documents/scientific/NPS_Report.pdf.

[4] The last figure includes six substances to be yet verified.

[5] Countries that have reported the emergence of NPS after mid-July 2012 include Austria, Belarus, Cambodia, Czech Republic, Denmark, Eritrea, Estonia, India, Myanmar, Qatar, Republic of Korea, Sudan, Sweden, Syrian Arab Republic, Tanzania, United Arab Emirates, Yemen and Zambia.

11. The international expert consultation, a closed meeting held in Vienna from 3 to 5 September 2013, set the scene for interactive discussions on possible international responses to the problem of NPS. The aim of the consultations was to share information on NPS, including information on their identification, emerging trends, mechanisms to monitor NPS as well as experiences in adopting effective responses to address the unique challenges posed by them, and to discuss ways of moving forward effectively within the context of the existing drug control conventions.

12. The expert consultation brought together over 60 participants from international and regional organizations as well as subject-matter experts from national drug control agencies, health departments and law enforcement agencies of selected countries. Participating international and regional entities included the Secretariat of the International Narcotics Control Board (INCB), INTERPOL, World Customs Organization (WCO), World Health Organization (WHO), UNODC, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the Organization of American States (OAS) and the Organization for Security and Cooperation in Europe (OSCE).

13. The Deputy Executive Director of UNODC and Director, Division for Policy Analysis and Public Affairs opened the consultation and the agenda was outlined by the Chief of the UNODC Laboratory and Scientific Section. The expert meeting was conducted through presentations and question-and-answer sessions that provided room for an interactive discussion on possible international responses to the challenge of NPS.

14. The consultation served as a forum to share information on the existing provisions of the international drug control conventions, specifically the procedure for changes in the scope of control and implementation of control measures; monitoring mechanisms at the national, regional and international level, in support of the substance notification process under the international drug control conventions; experiences on innovative legal approaches adopted at the national level to control new substances, highlighting current challenges; and current and proposed responses to the challenge of NPS by participating international and regional organizations.

15. Within the scope, the expert consultation considered WHO's risk assessment process and its challenges, including those related to data collection; a historical review of the provisions under the international drug control treaties and changes in the scope of the control of substances; the role of the INCB in monitoring implementation of, and promoting compliance with, the provisions of the conventions by the Parties; national, regional and international approaches in monitoring of new psychoactive substances; legal responses to the NPS problem by Member States, in support of the international drug control system; and specific responses to the NPS problem by international organizations such as INCB, INTERPOL, UNODC, WHO and WCO. Based on experiences of individual countries and regions and under the umbrella of the international drug control mechanisms, participants discussed possible responses to countering the threat posed by NPS.

III. World Health Organization's risk assessment process and related challenges

16. The 1961 Convention and the 1971 Convention delineate a clear role for the WHO for carrying out risk assessment based on medical and scientific evaluations as well as for issuing recommendations to the CND on changes in the scope of control of substances, where appropriate. This constitutes the first step towards international control. The WHO stresses an objective approach by looking at risks as well as benefits of a particular drug, thereby balancing the need to place substances under control against public health considerations.

17. The risk assessment process requires WHO to examine the harmful effects of the substance in question and to determine whether the substance is liable to similar abuse and is productive of similar ill effects as other substances already placed under international control. The initiative to amend any of the schedules of the international drug control treaties through a notification by WHO entails several steps, including convening the Expert Committee on Drug Dependence (ECDD), where the need for a change in the status of a substance is discussed.

18. The preparative phase, which begins almost a year prior to the ECDD meeting, consist of activities such as setting the agenda, conducting scientific literature reviews, peer reviews and reports by Members, including recommendations on the change of the scope of control of substances. For purposes of data collection, analyses and reporting, and in order to maximize the information provided to the ECDD, a questionnaire-based survey for Member States is conducted before the end of the year prior to the ECDD meeting.

19. The meeting of the ECDD brings together members of expert panels, temporary advisers, observers including the INCB and UNODC, and the WHO Secretariat. Following the recommendations of the ECDD, the Director-General of the WHO makes a recommendation to the United Nations Secretary-General on the change of scope of control of the substances considered. Only after this process is completed a substance may be put under international control and/or have its scope of control changed.

20. In order to issue recommendations, WHO makes use of available clinical and public health data combined with data on the medical use of the respective substance. WHO makes decisions contingent upon the quality of the evidence available, which may directly translate into the strength of the issued recommendation. The availability of data is a major challenge in the risk assessment process. Additional challenges encountered by WHO include the resource intensity of the ECDD process and the lack of consistency in terminologies, whose variation is magnified with different languages.

IV. A historical review of the provisions under the international drug control treaties and changes in the scope of the schedules

21. Established in 1946, the mandate of the CND lies in assisting the Economic and Social Council (ECOSOC) in supervising the implementation of the international drug control conventions. Decisions to change the scope of control of

substances are made by the CND, it considers proposals to add, transfer or delete substances from the schedules. Any amendment to the scope of control of substances under the international drug control treaties follows a three-stage structure, involving notification, risk assessment and international control measures, if any.

22. The notification procedure initiates the process of reviewing the scope of control. Whenever a Party or the WHO has information relating to a substance not yet under international control, which in its opinion requires an amendment to any of the schedules of the conventions, it shall notify the Secretary-General and furnish him with the information in support of that notification. The Secretary-General transmits such notification and necessary information to the Parties, to the CND, and, where the notification is made by a Party, to the WHO. As of now, the WHO has submitted the vast majority of notifications with only few submitted by Member States.

23. The conventions assign the responsibility of carrying out the risk assessment to the WHO. This medical and scientific evaluation is carried out by the WHO ECDD and is described in detail in the "Guidance on the WHO Review of Psychoactive Substances for International Control."[6] WHO's assessment is determinative as to medical and scientific matters and the CND may consider the economic, social, legal, administrative and other factors communicated to it by the Parties. It may also decide to seek further information from the WHO or from other sources. The Commission decides whether to place a substance under international control and can make changes to the schedules only in accordance with the recommendations of the WHO. The CND may however, decline to make the changes recommended by WHO.

24. Placing a substance under the international control regime may sometimes need to be expedited to prevent harm. Both, the 1961 as well as the 1971 Conventions follow the example of earlier narcotic treaties and provide for provisional control measures pending the completion of the regular procedure for placing a substance under international control. It was noted that to date, provisional control measures which are analogous to temporary bans for NPS currently employed by a number of Member States, is provided for under both conventions, but have never been fully employed in practice.

V. Monitoring the implementation of, and promoting compliance with, the provisions of the conventions by the Parties

25. The INCB monitors the implementation of, and promotes compliance with, the provisions of the aforementioned international drug control conventions, by the Parties. In cooperation with Governments, it is mandated to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes; to ensure their availability for such purposes; as well as to prevent illicit cultivation, production and manufacture of and illicit trafficking in and use of, drugs. In general, control measures under the 1961 Convention and the 1971 Convention are similar, but not identical. With each convention, substances are grouped in four schedules with varying degrees of strictness of controls.

[6] http://apps.who.int/medicinedocs/documents/s17538en/s17538en.pdf.

26. The INCB is also mandated, under the United Nations Convention against Illicit Trafficking in Narcotic Drugs and Psychotropic Substances of 1988, to establish an assessment of substances used in the illicit manufacture of narcotic drugs or psychotropic substances for scheduling as precursors. The assessment carried out by INCB is determinative as to scientific matters. Subsequently, the CND decides, upon the recommendation of the INCB, to place chemicals frequently used for the manufacture of illicit drugs, under international control as precursors.

VI. Monitoring of new psychoactive substances: national, regional and international approaches

A. National level

27. Fuelled by the emergence of new trends and behaviours related to the abuse of traditional drugs as well as by the fact that trafficking and use of NPS has not yet been controlled under the international drug control conventions, Colombia recently developed a national early warning system (EWS). This is modelled on experiences of regional and international organizations and tailored to the local context. The Colombia EWS has the objectives of reducing health and safety risks, creating a platform for the exchange of information, strengthening controls, generation of timely and more opportune preventive actions, and the collection of scientific data as a basis for guiding public policies.

28. The Swedish National Institute of Public Health (SNIPH) and the Medical Product Agency (MPA) are commissioned by the Government to collect and assess information on NPS as a basis for considering the need for regulation. Sweden's monitoring activities and related data collection is carried out by the Network for the Current Situation on Drugs (NADiS), set up in 2000 with the aim of facilitating inter-agency information exchange on NPS, functioning as a reference group to the SNIPH and MPA and thus serving as a basis for national scheduling decisions and initiatives by the Government. A significant feature of the NADiS system is its online classification document, which enables a rapid procedure for NPS classification. The typical duration for the issuance of a classification ranges from one to three months.

29. In 2003, Denmark joined the NADiS network, followed by Norway in 2004, Finland in 2006 and Iceland in 2011, thereby creating the Nordic-NADiS. This cross-border collaboration avoids overlapping activities and serves as a focal point for early detection, collection and exchange of information, knowledge and experience, with the ultimate aim of NPS regulation at the national level. Appointed contact points have access to the system enabling a prompt exchange of information and new data.

B. Regional level

30. Initiated by the WCO Regional Liaison Office in Asia and Pacific (RILO AP), project *CATalyst* acts as a platform for sharing information on NPS seizures. With an initial timeframe of six months (July to December 2013), the project was designed to serve as a catalyst for NPS control in the Asia-Pacific region. RILO AP

coordinates the sharing of NPS information (seizure/notifications) through its Single Contact Points in participating Member States. Divergent national approaches in legislation allow for loopholes and proliferation of NPS and pose a challenge to the efforts of RILO AP. The diversity in types of NPS and lack of resources pose a challenge to the identification of new substances. It was noted, that online sales of relatively small amounts of NPS contribute to an anonymous and readily available turnover of substances, which are not easily captured by this approach.

31. Due to an expanding group of NPS, posing a health threat and a challenge to law enforcement, the WCO Regional Intelligence Liaison Office for Eastern and Central Europe (RILO ECE) launched project *SMART* in 2011. The programme aims at drawing attention to the increased popularity of NPS and at facilitating collection and exchange of information. Throughout the operational phase of *SMART* (August to December 2011) data collection was conducted through CENcomm, a WCO platform for secure exchange of law enforcement data. Project *SMART* identified the important role of the Internet in supply of NPS and recognized regular mail shipments as one of the main distribution methods. It also noted that different laws in various countries made it difficult to find a common approach for the prosecution of violations. The second phase of the project, *SMART II*, was launched in September 2013.

32. The European Union's approach to the monitoring of NPS through the European Early Warning System consists of three phases. At the first stage, information exchange is conducted on the basis of specific guidelines and information is transferred through ad hoc reporting forms, biannual early warning system reports and a joint report. The second step, a risk assessment, is likewise regulated through formalized guidelines and provides risk assessment reports. The first two stages provide the basis for the Council of Europe decisions on control of NPS. Overall, the EU has experienced changes in national legal responses since 2009. While some countries have modified existing drug laws by introducing group definitions and temporary controls other have employed non-drug laws, such as those pertaining to consumer safety, medicines or health protection, to effect control.

C. International level

33. In the context of international approaches, UNODC reported progress on the first Global Early Warning Advisory (EWA) on NPS, launched on 26 June 2013, pursuant to CND resolutions 55/1 of March 2012 and 56/4 of March 2013. The latter specifically urged UNODC to continue facilitating timely and comprehensive sharing of information on NPS including analytical methodologies, reference documents, mass spectra and trend analysis data on NPS. The EWA targets three main beneficiaries: laboratories, law enforcement and policy makers/organizations. Through the website (www.unodc.org/nps), registered users can access relevant information, as well as conduct trend analysis of NPS data.

34. With a view to providing a global reference point and early warning on NPS, the EWA administered by the UNODC Laboratory and Scientific Section through the Global SMART Programme, issues updates in the form of *NPS briefs* by email, on its website and in Global SMART publications. The EWA provides information

on different NPS groups, legislative responses by Member States to counter the challenge of NPS, and user-related studies. In addition, it provides bibliographic resources to inform Member States, organizations and the scientific community on recently available methods for the analysis and identification of NPS and published literature on the toxicology, pharmacology, use and treatment of NPS. More broadly, the Laboratory and Scientific Section works on NPS in the areas of knowledge enhancement, capacity building, global assessment of the NPS situation and assistance to forensic laboratories through its International Collaborative Exercise programme.

VII. Legal responses to support the international drug control system and related challenges to new psychoactive substances

A. Analogue, generic and temporary legislation

35. Information on analogue legislation was provided based upon the example of the United States. According to the Controlled Substance Analogue Act of 1986, a controlled substance analogue shall, to the extent intended for human consumption, be treated for the purposes for any Federal law as a controlled substance in Schedule I, thus enabling investigation. However, in an attempt to overcome the "human consumption" element, producers and traffickers of NPS employ the marketing strategy of labelling NPS products as "not for human consumption." The Act itself requires proof of substantial similarity both with respect to chemical structure and pharmacological effect of the NPS in relation to its analogue. The substantial similarity element often results in a battle of expert scientific witnesses at court and can be vigorously contested at all stages of prosecution. The prosecutions are resource intensive and unpredictable. Often constitutional issues, such as vagueness of the definition, come into play. Nevertheless, the Analogue Act has achieved many successful prosecutions: 39 prosecutions from 1991-2011 and another 218 from 2011 to date. Several challenges exist and may be exacerbated with the rapid spread of NPS. First, the Analogue Act is essentially suited to address a low volume of cases, whereas the current NPS landscape has undergone significant change. Second, it may not be a suitable measure to stem the seemingly ceaseless flow of NPS.

36. An overview over generic legislation was based upon Japan's experience with NPS. The appearance of new analogues of psychoactive substances since 2011 prompted the Japanese government to take countermeasures for their effective designation. The Japanese Ministry of Health, Labour and Welfare has committed itself to list NPS as Designated Substances with greater speed in order to rapidly recategorize these into narcotics under significantly stricter control. The control of new substances undergoes a three step process. The first step encompasses identification of unapproved or unauthorized pharmaceuticals, whereas the second step classifies them into Designated Substances with the aim of controlling their distribution. With the objective of prohibiting their distribution, possession and use, the third step renames the Designated Substance as narcotics.

37. The generic legislation used in the United Kingdom captures groups/families of related NPS, and anticipates future chemical modifications to the parent structure which have the potential to cause harm. Generic definitions were introduced in the

late 1970s and are generally regarded as having been successful in controlling nearly all NPS in the United Kingdom prior to implementation of controls in the EU. The benefits include a degree of legal certainty, good coverage and an immediate enforcement response if a "generic" NPS emerges later. It also provides the possibility of reviewing and expanding generic definitions. Relevant risks include enduring gaps that are being exploited by producers and traffickers; transparency of legislation for its enforcers, suppliers and users; possible difficulty in maintaining the link between scope and evidence base, and the scope of control inadvertently covering NPS with legitimate use.

38. The United Kingdom regulates temporary bans in the form of specific emergency provisions, so-called Temporary Class Drug Orders (TCDOs). Their purpose is to provide a quick response to NPS where there is little knowledge of harms in order to prevent the substance from gaining a foothold. TCDOs enable enforcement partners to take action and aim to balance the swiftness of response against the sufficiency of evidence. Following an initial assessment by experts, emergency provisions enable the control of an NPS for up to 12 months while the full range of harms is reviewed. The provisions are targeted at suppliers and producers specifically for controlling import, export and production. However, they do not criminalize a simple possession offence as they are not aimed at penalizing the users when the full range of harms is not yet known. TCDOs send an immediate and strong political message while monitoring the market reaction to inform follow-up controls. Despite their usefulness as a temporary control tool, they are perceived to be highly reactive and often with a limited evidence base. TCDOs also have the potential to increase the curiosity of the public towards certain substances. The risk of substances falling outside of control after the temporary period has elapsed is a possibility.

B. Other national responses to new psychoactive substances

39. The Controlled Drugs and Substances Act (CDSA) provides for the control of NPS in Canada. The CDSA contains six schedules which set out the specific substances under control. The process from assessment to final publication of a regulation typically takes 18-24 months. In some cases it is possible for an existing schedule entry to include NPS by virtue of the fact that the substance in question is a salt, derivative, isomer, analogue or salt of a derivative of a substance already listed in one of the schedules. This is determined on a case-by-case basis via the status decision process that assesses the chemical structure and/or pharmacological activity of the NPS against that of existing controlled substances. The challenge is that in order for a substance to be deemed a similar synthetic preparation, there has to be scientific data showing that the substance has a similar pharmacological activity profile. Often, such scientific data are not available. The Canadian Food and Drugs Act (FDA) definition of a drug includes any substance that modifies organic function. Under the FDA and its regulations, it is illegal to sell a drug that has not been authorized for sale by Health Canada. This relative "catch-all" approach has allowed Canada to deem the sale of several substances to be illegal.

40. On 18 July 2013, New Zealand's Psychoactive Substances Act came into effect. The legislation prohibits the importation, manufacture and supply of all psychoactive substances, only allowing the sale of those that can meet safety and

manufacturing requirements. The new legislation provides a long-term solution as it restricts all NPS by default and only allows the sale of those that have been approved by a regulatory body. Accordingly, the government will no longer have to demonstrate that a product is harmful before restricting it. The onus of proof that a product is low risk will be on manufacturers. This process is similar to that used with medicines or other potentially hazardous substances and requires that mechanisms exist for sponsors to prove safety.

41. In order to effectively combat the spread of NPS, the Russian Federal Drug Control Service has developed and implemented a new system to identify NPS since 2012. The system establishes controls through the identification of a single psychoactive basis for a large group of synthetically modified chemical substances. In contrast to individual scheduling, this strategy allows control of the circulation and turnover of whole groups of substances at once. Since its inception, it has established controls of over more than 500 NPS. The system introduces a special definition for derivatives of narcotic drugs and psychotropic substances, which is intended to establish criteria for identifying substances by excluding drugs and substances of biogenic nature. Currently, there is also an initiative for the establishment of a temporary ban on the sale of NPS.

C. Efforts by perceived source countries

42. Although China and India are frequently perceived as source countries of NPS, a number of European countries such as the Czech Republic, Hungary, the Netherlands, Portugal, Spain, Ukraine and the United Kingdom have also been named as potential NPS origin countries. Sources are reported by the respondents to the UNODC 2012 questionnaire on NPS and have not been validated scientifically as manufacturing/production sites.[7]

43. Since 2012, China has received a number of requests from some countries to investigate the sources of NPS exported from its territory. The distribution of NPS follows a pattern where substances, which are not controlled in China but in other countries, are ordered/purchased by foreign clients or drug traffickers and exported abroad, mostly by mail. Difficulties in combating such activities are rooted in the different legislations of various countries. In 2012, China carried out a multi-agency research on NPS and initiated temporary control mechanisms. China aims to strengthen domestic administrative intervention in the form of stricter domestic punishment; increase efforts on education, warnings and persuasion; and institute more rigorous control on production and demand. The government further considers inter alia initiatives to tackle drug crime on the Internet, the sharing of operational information on relevant NPS cases, and enhanced communication and sharing of legislation as essential components of a successful response to NPS.

44. Drug control regulation in India is generally based on the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985; the Customs Act, 1962; the Drugs and Cosmetics Act, 1940; and the Penalties Most Stringent under the NDPS Act 1985. NPS reported in India comprise of ketamine and mephedrone. The export of ketamine requires a so-called *No Objection Certificate* of the Narcotic

[7] "*The challenge of new psychoactive substances*," available online: www.unodc.org/documents/scientific/NPS_Report.pdf.

Commissioner and an attempt to export ketamine illegally would result in confiscation under the Customs Act. In addition, ketamine was placed under Schedule H of the Drugs and Cosmetics Act and thus requires a prescription for its sale. In February 2011, ketamine was notified as a psychotropic substance under the NDPS in effect controlling its manufacture, possession, sale, purchase, use as well as import and export. With regard to mephedrone, the authorities have reported two seizures to date: over 1200 kg of mephedrone at a manufacturer's premises in Mumbai in 2011 and a seizure of 30 kg each in Delhi and Mumbai in 2013.

VIII. International responses to the challenge of new psychoactive substances

45. As part of its mandate on control of precursors, INCB supports governments in preventing diversions and in investigations. Within this framework, it monitors legitimate trade, assesses chemicals for control, supports investigations and provides forums and platforms for intelligence sharing. Complementary to the global system of data collection on NPS that UNODC has put in place through its EWA, INCB is currently working to support operational responses carried out by Member States to respond to this threat. To that end, the existing Precursors Incident Communication System (PICS), a secure online tool developed by INCB to enhance real-time communication and information sharing between national authorities on precursors incidents, is being enhanced to develop actionable intelligence on NPS at the global level and prevent such substances from reaching consumer markets.

46. INTERPOL's intelligence analysis is carried out for trends, modus operandi, networks, methods of concealment and routes of criminal activities involving NPS. Information is then shared with Member States, whereupon investigations are coordinated. Often NPS are seized in small amounts and subsequently not reported by most countries. Accordingly, the division between classic drugs and NPS constitutes one of the main challenges to be worked on at an investigative level, not only because of the different markets for the substances, but also due to the divergent criminal potential of NPS. INTERPOL identified the problematic role of the Internet as a marketing platform and distribution channel for NPS and subsequently a need for specialized investigators.

47. The WCO aims to facilitate NPS-related operations among its Member States. The WCO Members are supported by 11 RILOs (refer to para. 27 and 28), 154 NCPs and customs offices at the national level. WCO's CEN (Customs Enforcement Network) represents a central global depositary of enforcement-related information, whose data are accessible to customs administrations. External organizations can access the CENcomm, a secure messaging system for cross-border operations. The CEN database features 3805 cases of NPS seizures made/reported between January 2012 and July 2013.

48. The WHO outlined its strategy for evaluating NPS stressing the need for proper health risk assessments. It discussed the various options for response including prioritization of the substances to be evaluated, expediting the process of review, alignment with the meetings of the CND and proactive data collection.

49. With regard to prioritization and speeding up of the process, WHO reported on the use of limited expert consultation, the UNODC report on the challenge of new

psychoactive substances, and data from forensic laboratories, EMCDDA and countries on harm, in identifying substances for review. It is also considering critical reviews without pre-reviews for substances with no medical use, based on limited expert consultation.

50. The WHO recognizes the lack of data on public health and social aspects of NPS as a major challenge in the risk assessment process. It is pursuing a more vigorous attempt at collecting data from Member States including revision of its questionnaire and utilization of data collected by INCB and UNODC.

IX. Options for response in addressing challenges

A. Control of new substances under the international drug control conventions

51. The possibility of further maximizing the use of the tools available under the international drug control conventions was noted. Historically, only few notifications have been initiated by State Parties since 1961. In addition, provisional control measures under the international drug conventions, analogous to temporary control measures currently used in some countries have not been fully employed in practice. Several experts recommended the development of simplified guidance material for Member States on the scheduling process.

52. The rapid and unprecedented speed of evolution and spread of new substances makes the time management for control process a real challenge. It was also acknowledged that substance control could be a trigger for proliferation and diversification. Therefore, efficiency and timeliness of the process from initiation/notification to recommendation of control measures is of great importance. Experts considered the option of synchronizing the respective process cycles of the WHO and the CND, including the possible use of the reconvened sessions of the CND for considering urgent scheduling issues, if deemed necessary. Although WHO does not possess a provision for emergency procedures, quick and decisive action is possible in cases of urgency. The resource intense nature of the work of the ECDD was noted.

53. Regarding prioritization of substances for review/scheduling, WHO has developed a prioritization strategy for risk assessments within chemical groups of NPS, following the prioritization made in the 2013 UNODC report "*The challenge of new psychoactive substances*".[8] This approach could be further supported by the UNODC Early Warning Advisory, taking into consideration existing harm data available from regional monitoring mechanisms such as the EMCDDA early warning system. Experts called for the sharing of information with Member States, so as to include them in efforts aimed at process prioritization and ensuring standardization of approaches.

[8] "*The challenge of new psychoactive substances*," available online: www.unodc.org/documents/scientific/NPS_Report.pdf.

B. Detection and identification of new psychoactive substances

54. While detection and identification of emerging substances is the first step in assessing potential health risks, many stakeholders lack the requisite capacity. Detection, identification and structure elucidation of NPS remain a major challenge for laboratories which affects the generation of evidence-based data/information and consequently the effective monitoring and implementation of control. In addition, the rapidly changing scene with respect to newer NPS constitutes an added challenge. The need to support the enhancement of the capacity of forensic laboratories was considered critical in this regard.

55. UNODC, through its Early Warning Advisory and the International Collaborative Exercise would continue to support laboratories in the identification of substances through sharing of analytical methods and data, including reference spectra and as part of its chemical reference standards programme.

C. Addressing data challenges

56. Experts identified a number of issues to be addressed regarding the collection and sharing of data. These included the need for standardization of terminology; avoidance of duplication in data collection by international and regional organizations; disparities in national capacities e.g., in forensics and toxicology; the need for guidance on development of national early warning systems including definition of minimum criteria/indicators; and the scope of information disclosure when issuing early warnings.

57. Collection of health-related data from multiple facilities across the world has many additional challenges such as lack of diagnostic capacities and weak data collection systems. Experts suggested the consideration of modern chemometric methods as another option in toxicological evaluations to aid the risk assessment process in view of the large number of candidate substances.

58. Experts identified the need for enhanced cooperation/collaboration between the various monitoring systems, particularly in the collection and sharing of information at regional and international levels. Participants acknowledged that this would facilitate more efficient data collection and alleviate the extra burden placed on countries in the separate reporting of similar data to multiple organizations. EMCDDA and UNODC were urged to consider sharing of relevant information in this regard.

59. With regard to data on potential risks and harms of new substances, the UNODC EWA together with WHO should explore further how the data collection systems could be better harmonized and improved. Experts discussed the potential for enhancing data collection by the UNODC EWA to also include pertinent health-related data, which could contribute to the risk assessment by WHO. Prior to its ECDD meeting, WHO collects data using a questionnaire and ways of collaboration with UNODC and INCB need to be explored.

60. Experts recognized the role of the UNODC Early Warning Advisory as a knowledge hub for the international community regarding NPS. It could be used as

a platform to collate existing information, ensure effective coordination at a global level and subsequently simplify the burden on governments for reporting data.

D. Reducing supply

61. Supply reduction activities, particularly law enforcement operations are an important facet of the response to the NPS problem. Experts noted the significance of current and proposed initiatives to share information on NPS by the INCB, INTERPOL and WCO, including its Regional Intelligence Liaison Offices in Asia and the Pacific and Eastern and Central Europe. The need for coordination of these intelligence-led operational activities was raised, also taking note of the mandates of the various organizations.

62. The Internet was identified as a challenging distribution channel for NPS. It presents an easy, anonymous, low risk and low cost way to avoid national legislation. Experts identified the need for raising awareness of this issue, enhancing international cooperation, including but not limited to, the sharing of information and appropriate training for law enforcement officers.

E. Prevention and demand reduction

63. Experts identified the need for a balanced approach, addressing both law enforcement and health issues. Accentuation and articulation of prevention efforts and health care should be incorporated into strategies to counter the problem of NPS and could help in addressing the "aura of legality" around NPS. Education on NPS should also be provided in order to sensitize first respondents. UNODC and WHO could work in collaboration on information regarding prevention and demand reduction to be included in an updated version of UNODC's fact sheet on NPS.

F. National legislation

64. While some countries have been innovative in introducing new legislation to address the NPS problem, there was acknowledgment of the continuing challenges faced by different countries in implementing the various national legislations. Experts advised on the need for a judicious balance between available scientific evidence and legislative action in an evidence based manner for more timely control of the emergence of NPS on the market, to minimize public health harm. Experts also observed that differences in country-specific legislation and country capacities for implementing these, particularly between source, transit and destination countries presented opportunities for trafficking in NPS and posed a major obstacle for effective law enforcement interventions.

65. Experts would wish for access to existing country specific legislations in order to assess the pros and cons of the respective approaches. In this context, the UNODC Early Warning Advisory will continue to serve as a global focal point and provide a platform for cataloguing and sharing legislative information.