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

UNODC-WHO Expert Consultation on New Psychoactive Substances, Vienna, 9-11 December 2014

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Summary

The UNODC-WHO Expert Consultation on New Psychoactive Substances, held in Vienna from 9 to 11 December 2014, served as a follow-up to the expert consultation in 2013 and to the 36th meeting of the WHO Expert Committee on Drug Dependence (ECDD). The meeting set the scene for discussions on the challenges identified for the evaluation and risk assessment of NPS; exploration of mechanisms for improving the collection of data on NPS, including but not limited to existing mechanisms, such as the WHO Member States questionnaire, the UNODC Annual Report Questionnaire (ARQ) and the UNODC Early Warning Advisory (EWA); development of a strategy for the identification of the most problematic substances through international, regional and national monitoring systems; and the identification of possible criteria and methods for the prioritization of NPS. As a result of the discussions, experts considered potential options for response to the challenges posed by NPS at the national and international level.

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I. Introduction and background

1. The number and diversity of new psychoactive substances (NPS) with potentially serious risks to public health has continued to increase in recent years. Within the last decade, the use of NPS has also increased rapidly, 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 represents a significant policy challenge for Member States and continues to be of international concern. While the emergence of a large number of NPS and their geographic expansion continue, different patterns in their emergence and persistence on the market have been identified, with the emergence of some NPS being transient in nature. The rapid proliferation of NPS, their rapid turnover and the circulation of different substances in different parts of the world make prioritization for evaluation difficult, albeit a necessary undertaking.

2. In May 2013, the first comprehensive UNODC report on NPS "The challenge of new psychoactive substances",[1] provided for the first time global data on the emergence of these substances. By December 2014, the number of NPS reported by Member States to UNODC rose to over 540 substances from 251 by mid-2012 and 166 in 2009, outnumbering the total number of psychoactive substances currently controlled under the 1961 Convention and the 1971 Convention. The global spread of these substances has also increased with 95 countries and territories reporting the emergence of NPS by December 2014, up from 70 countries and territories that had reported NPS by mid-2012.[2]

3. The international expert consultation on NPS, organized by UNODC under the umbrella of its Global Synthetics Monitoring: Analyses, Reporting and Trends Programme (SMART), in Vienna from 3 to 5 September 2013, served as a forum to discuss for the first time potential options for response to the problem of NPS at the international level. Experts identified several challenges related to NPS, including: their emergence and continuous evolution, and the coverage and persistence in individual regions. The paucity of data on NPS, particularly on potential risks and harms, and the implications for the prioritization process for evaluation and risk assessments, was identified.[3]

4. The UNODC-World Health Organization (WHO) expert consultation on NPS, organized in Vienna from 9 to 11 December 2014, served as a follow-up to the expert consultation in 2013 and to the 36th meeting of the WHO Expert Committee on Drug Dependence (ECDD). The meeting set the scene for discussions on the challenges identified for the evaluation and risk assessment of NPS; exploration of mechanisms for improving the collection of data on NPS, including but not limited to existing mechanisms, such as the WHO Member States questionnaire, the UNODC Annual Report Questionnaire (ARQ) and the UNODC Early Warning Advisory (EWA); development of a strategy for the identification of the most

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

[2] Countries that have reported the emergence of NPS after 2012 include Armenia, Burkina Faso, Cayman Islands, Côte d'Ivoire, Luxembourg, Montenegro, Peru, Seychelles, Sierra Leone, Slovenia, Sri Lanka and Ukraine.

[3] E/CN.7/2014/CRP.1.

problematic substances through international, regional and national monitoring systems; and the identification of possible criteria and methods for the prioritization of NPS, with the objective of facilitating effective responses at the international level.

5. The UNODC-WHO 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), International Criminal Police Organization (INTERPOL), World Customs Organization (WCO), World Health Organization (WHO), UNODC, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the European Police Office (Europol) and the Organization of American States (OAS).

6. The Director, Division for Policy Analysis and Public Affairs, UNODC and the Director of the Essential Medicines and Health Products Department of WHO opened the consultation. The agenda and organization of work was outlined by the Chief of the UNODC Laboratory and Scientific Section. The expert consultation was conducted through presentations, question-and-answer sessions and interactive discussions both within working groups and at plenary. The format provided the opportunity for open discussions on the development of tools for NPS prioritization and identification of minimum criteria for NPS evaluation.

7. The expert consultation considered the challenges for the evaluation of NPS within the WHO ECDD evaluation mechanism, based on the experiences of the first review of NPS at the 36th Meeting of the ECDD. At that meeting, the Committee was tasked with assessing a large number of substances within a short time frame, and within the flexibility of the Guidance on the WHO Review of Psychoactive Substances for International Control. Existing international data collection mechanisms were reviewed and experts suggested approaches to strengthen collaboration at the national, regional and international level in order to facilitate the availability of the information required to prioritize and evaluate NPS. In addition, improved methods for obtaining data were identified, particularly for the assessment of dependence potential, abuse liability and both individual and public health harm associated with these substances.

8. During the meeting, experts acknowledged the different patterns in the emergence and persistence of NPS at the global level, such as the striking heterogeneity at the country level regarding the number and type of NPS and the transient nature of some NPS. This makes it necessary to develop a strategy that allows for the identification of minimum criteria/indicators for the selection of the most problematic substances. It was recognized that it is not feasible, and probably not necessary, to address all NPS at once.

9. While the international community strives to adopt a strategy for NPS prioritization, national and regional efforts have advanced in that direction. A number of countries and specific regions shared their experiences in the process of prioritization of NPS for the purpose of control.

II. Prioritization of NPS at the national and regional level

National

10. The evidence of harm and risks to public health were recognized as major triggers for the process of NPS prioritization in many countries, including France, Latvia, the United Kingdom of Great Britain and Northern Ireland and the United States of America. It was noted however, that even the consideration of harm varies from "evidence of harm" through "actual or likely harmfulness" to "serious harm" among these countries. The challenges related to the collection of evidence of harm were acknowledged. These include the paucity of data on serious adverse effects (which often lack identification by toxicological analysis) and the shortcomings in sharing data and knowledge between institutions.

11. To address these challenges at the national level, experts suggested extending the criteria and data sources used in the process of NPS prioritization, to include: NPS related harm data from toxicovigilance systems, forensic laboratories, emergency departments; seizure data from the different law enforcement authorities; and data on NPS use from open online sources. The need to centralize information through national Early Warning Systems was also highlighted by the experts.

Regional

12. Sweden and the EMCDDA shared experiences on the prioritization of NPS for the purpose of control in the Nordic countries and in the European Union, respectively. Similar to the scenario at the national level, "serious adverse events" were presented as a key indicator in the process of NPS prioritization.

13. In the framework of the European Union, "serious adverse events" related to NPS are reported by Member States to trigger the process of NPS prioritization. Sources of data on serious adverse events include hospitals, analytical and forensic toxicology services, poison information centres, hospital emergency departments, pathologists, coroners and from open sources of information (media monitoring, scientific and medical literature, social networks/media). Once the data has been validated and if so required, a joint report is prepared by Europol and the EMCDDA. Based on this report, the Council may request a "risk assessment" of health and social risks and may make a decision on the control of the substance, in accordance with the Council Decision 2005/387/JHA.

III. Challenges for evaluation of NPS

14. The 1961 Convention and the 1971 Convention delineate a clear role for WHO through its ECDD for carrying out risks assessments of substances 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. The 36th Meeting of the ECDD held in 2014, represented the first time the international system has had to deal with the phenomenon of NPS.

15. The ECDD noted that some NPS show significant harm, have no legitimate use, and have limited scientific and research use. Challenges identified during the recent review included: the paucity of data/evidence required to recommend

international control, especially for the assessment of dependence potential, abuse liability and both individual and public health harm; and the fact that there are only limited systematic studies with most information only available from case reports.

16. The experts recognize that the data situation is unlikely to improve in the immediate future due to: lack of laboratory capacity in many countries for the identification of NPS, especially in the health sector; limited data related to criminal activity; and poly-substance use (several NPS are used in combination with traditional drugs) which renders the assessment of the harm of individual substances very difficult.

17. Experts reflected on the approach of the ECDD during the period 1984 to 1990 when the number of substances controlled under the 1961 and 1971 Conventions increased by 71. The data limitations encountered during that period were reviewed in a bid to identify potential approaches to addressing the current challenges in assessing NPS.

IV. International data collection systems and prioritization of NPS

18. Experts acknowledged that existing mandated data collection tools such as the UNODC ARQ and IDS currently collect limited data on NPS. With their main focus being on substances under international control, only limited information on certain aspects of NPS has become available through these data collection tools.

19. Up-to-date data on the emergence and geographic distribution of NPS at the international level is collected through the UNODC EWA, which also provides substance-specific information. However information on potentially relevant indicators for NPS prioritization such as seizures, drug use prevalence and health-related data are currently not collected through this system.

20. The health-related data needed for evaluation of substances by the ECDD are collected by WHO, through its Member States questionnaire. However, there is the limitation that response rates and the quality and quantity of information provided for NPS do not always meet the information needs of the ECDD.

21. The existing aforementioned data collection tools were reviewed, taking into consideration the type of information needed to facilitate the process of prioritization and evaluation of NPS. Opportunities for improving the tools for collecting data on NPS, in cases where such flexibility exists, were discussed, in addition to possible improvements on quality and quantity of data reported through existing mechanisms.

22. Challenges related to the collection of NPS data, such as the difficulty of registering seizures due to NPS preparations containing multiple substances and the difficulty in reporting the number of deaths related to substances under evaluation due to the problem of establishing a causal relationship between fatalities and specific substances were also acknowledged.

V. Options for response at the national level

A. NPS data collection

23. Experts stressed the need for raising awareness among Member States of the importance of collecting information on harm caused by NPS and their prevalence of use for the purpose of prioritizing and evaluating NPS at both the national and international level.

24. Experts called on UNODC and WHO to advocate for the establishment (or strengthening) of information systems, as well as of laboratories and clinical services, in order to enhance collection of data on dependence and abuse. They further called for more efficient collection of pharmacovigilance data at the national and international level and increased collaboration with poison control centres and other scientific networks.

25. The minimum criteria to be included in data collection tools on NPS were identified as: numbers of deaths; poisoning events (forensic and/or clinical); and reports of injecting drug use, prevalence of use and acute toxicity. The importance of collecting data on seizures was also noted, as a useful tool for indicating the presence of a substance in one or more countries.

26. With regard to harm, data on severe adverse events could be collected through forensic toxicology and hospital services, emergency room admissions, poison control centres, treatment facility centres and case reports/series reported in scientific medical literature. These could be complemented by data on potential harm, drawn from non-clinical literature such as animal studies and from non-traditional data sources, including Internet-based information from drug forums and chat rooms or online drug websites.

27. Noting the significance of early warning systems (EWS) in the collection of NPS data, the need for promoting the development of national and regional EWS was identified. Experts stressed the importance of capacity-building activities for setting up EWS and called on UNODC to continue raising awareness on NPS and develop guidelines on establishing national and regional EWS.

28. With most countries already collecting data for monitoring medicines and vaccines, it was suggested that national data collection of NPS could be based on these systems. Data from these systems should be aggregated at the national levels and where appropriate collected at a global level through the UNODC EWA, taking into consideration existing regional mechanisms.

B. Improving forensic laboratory capacity

29. Experts recognized that the difficulties in detection and identification of NPS present a major challenge for creating a comprehensive global evidence base for prioritization. They further noted the disparities in national forensic laboratory capacities e.g. in toxicology.

30. Experts recommended the provision of technical support to countries in need, to strengthen their laboratory capacity. Such support includes promoting the use of

standardized methodologies for the identification of substances and making available chemical reference standards.

VI. Options for response at the international level

A. Data exchange between international and regional organizations

31. Experts encouraged closer coordination and collaboration between UNODC and WHO with the two organizations exploring the feasibility of complementary activities and the use of joint questionnaires for annual reporting on NPS, with defined respective roles for data collection on law enforcement and health issues.

32. Experts further encouraged information-sharing between EMCDDA, UNODC WHO and other agencies involved in data collection, as well as the alignment of terminology and harmonization of indicators used in the process of prioritization, and highlighted the complementarity of roles in data collection and analysis. Institutional cooperation and relationship building were also discussed as means to improve quality and availability of data at the global level.

B. Improving existing international data collection tools and systems

33. Experts recognized that while the ARQ could be a useful tool for the collection of data on NPS, it needs further enhancements and structuring of NPS related questions instead of only including such information in narrative questions. The IDS was recognized as a useful tool for collecting very recent data on NPS seizure, which could be used as a proxy indicator of the emergence of NPS at a global level. It was felt that further enhancement of the data collection tools may benefit from establishing national focal points dedicated to the national coordination of this type of data collection.

34. Recognizing the role of the UNODC EWA as a knowledge hub for the international community regarding NPS issues, experts indicated the need for the EWA to collect data on prevalence of use, harm-related information and health-related data, including but not limited to data from the WHO questionnaires. This would ensure effective coordination and avoid increasing the reporting load on governments.

35. The consultation noted that the data collection tools from UNODC and WHO could be improved by addressing the wording and structure of questions and their user-friendliness, taking into account the capacity of countries to complete the questionnaires. In addition, experts recommended better targeting of respondents to ensure high response rates, and quality/quantity of information.

36. Noting the need to enhance the collection of health-related data, particularly harm and prevalence of use data, which are also important in the context of the risk assessment activities of the WHO, experts considered that a system allowing the continuous flow of data would be much more efficient and adequate than the current use of questionnaires.

C. Exploring non-traditional sources of information

37. With NPS being a recent and emerging issue, traditional sources of information on prevalence of use, such as representative population-based drug use surveys are not available in most cases. Acknowledging the data gaps and unavailability of many standard indicators with regard to NPS, experts identified the need to use other sources of information as proxies for prevalence to understand the extent of the problem. This includes data from targeted surveys of drug users and sub-populations, Internet-based surveys and data collected through professional organizations such as the International Association of Forensic Toxicologists.

38. Experts noted the usefulness of non-conventional sources of information, such as the Internet (specifically social media and Internet-based drug user forums) as a tool to better understand the NPS market, while also cautioning about its limitations.

D. Phased approach to NPS prioritization

39. The collection of event-based data from countries may serve as a useful proxy indicator of the global NPS situation. During data collection at the national level, a substance may initially produce a basic level of concern, which will give rise to a more proactive monitoring approach. If the concern then grows, and there are a higher number of reports from multiple countries, it may reach a level of international relevance.

40. A phased prioritization process, for example one based on pre-selection followed by prioritization for international response, was considered in order to filter out the less problematic NPS. Evidence of harm or potential harm of a substance, and the prevalence (or proxies for prevalence) of its use, were identified as the two main criteria for consideration.

41. As an illustration of the decision-making process, an initial step would be to recognize the harm due to a substance. This would be followed by a refinement process using other indicators, such as those included under prevalence (or proxies for prevalence) of use. A subsequent step involving triangulation of data through a systematic review of complementary data on the prevalence of NPS on the market, including information on seizures, clandestine manufacture and test purchases would contribute to the validation of data by cross verifying the same information.

42. Such a process could reduce the risk of error, particularly of including substances of little relevance for the international drug control system, such as those considered to be localised in a particular area/country or with only a short-lived appearance in the market. Experts however recognized that in some cases, some NPS associated with serious health risks may lack data which could be used for prioritization.

E. Evaluation of NPS at the international level

43. Learning from the approach of the ECDD used to evaluate a large range of substances between 1984 and 1990 and from the recent first evaluation of new

psychoactive substances at the 36th ECDD meeting, experts discussed data limitations and potential approaches for addressing the data challenges in assessing NPS. The principle of "similarity", as outlined in Article 2, paragraph 4, of the 1971 Convention and in the Guidance on the WHO review of Psychoactive Substances for International Control (paragraph 53), was discussed and experts agreed that the evaluation of NPS might be more feasible, based on similarity to NPS previously reviewed by the ECDD.

44. The criteria in the Guidance on the WHO review of psychoactive substances for international control (paragraph 53) were reviewed to identify the minimum requirements to recommend scheduling of substances. It was noted that the evidence base required to determine the *capacity of a substance to produce a state of dependence*, as prescribed under article 2, paragraph 4, subparagraph (a), clause (i) of the 1971 Convention, needed some clarification and that this requirement provides some flexibility with respect to the level of data required.

45. Experts identified several criteria and mechanisms to carry out assessments of NPS in the context of limited data availability, based on two main groups of NPS.

Newly emerged substances

46. In view of the limited available evidence of dependence, it was recognized that several sources of information will need to be considered, including:

(a) Primary evidence for dependence, e.g. peer review data, clinical and laboratory data;

(b) Secondary evidence for dependence, e.g. non-published information on NPS such as from surveys data;

(c) Tertiary evidence for dependence, e.g. Internet sources (such as social media and drug user forums). While recognizing the particular importance and usefulness of Internet sources.

47. Additional evidence would also be required on:

(a) Central Nervous System (CNS) stimulation or depression;

(b) Whether the substances' abuse constitutes a public health problem and/or social problem (e.g. domestic welfare, child neglect, intoxicated driving), as well as whether the substance likelihood of abuse (e.g. seizure data) constitute a public health and social problem.

48. The assessment of toxicological significance was also discussed, particularly taking into consideration polydrug use associated with NPS. The use of a toxicological significance score, which tries to address the role of multiple drugs in the system at the time of death, was suggested as a possible approach. For determining the level of "risks" in scheduling decisions, experts proposed the consideration of the use of analytically confirmed toxicity as a critical element of "substantial" risk to public health. Finally, with regard to the nature and scope of data required for these substances, experts noted that such data could be obtained through early warning systems, clinical and non-clinical reports, toxicology data in casework and in some instances, on a case-by-case basis.

NPS similar to substances scheduled under the Conventions

49. Experts considered criteria which could be used to classify a substance as being of "similar abuse" and "similar ill effect" to a scheduled drug. These include:

(a) Similar abuse: mode of abuse, formulations, routes of administration, similar use setting and similar intended effect;

(b) Similar ill effect: clinical symptoms, fatal outcomes, common Internet reports.

50. Criteria for providing evidence that the substance's abuse constitutes a public health problem were also considered, and the marketing of the substance was cited as an example.