

EARLY WARNING SYSTEM

on New Psychoactive Substances
& Emerging Drug Phenomena

IMPLEMENTATION MANUAL



This project is funded by
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Cooperation Programme between Latin America, the Caribbean and the European Union on Drugs Policies (COPOLAD II)



European Monitoring Centre
for Drugs and Drug Addiction



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info@copolad.eu
www.copolad.eu

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Lead countries:

Spanish-speaking countries: Colombia and Uruguay
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European countries used as References: Portugal and Poland

Expert group:

Coordination: Jessica Ramírez (Uruguay)
Drafting: Jenny Fagua (Colombia)
Katerina Grohmannova (Czech Republic)
Héctor Suárez (Uruguay)
Leticia Keuroglan (Uruguay)
Revision: Ana Gallegos (EMCDDA)
Marya Hynes (OID/CICAD/OAS)
Viktor Mravčík (Czech Republic)
Graciela Ahumada (Coordinator of Component 1, COPOLAD II)

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ACRONYMS

CELAC	Community of Latin American & Caribbean States
CESAR	Center for Substance Abuse Research
CICAD/OAS	Inter-American Drug Abuse Control Commission/Organization of American States
CLEN	Customs Laboratory European Network
COPOLAD	Cooperation Programme between Latin America, the Caribbean and the European Union on Drugs Policies
DGPNSD	Spanish Government Delegation for the National Plan on Drugs
DIN	Drug Information Network
EDND	European Database on New Drugs
EMA	European Medicines Agency
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
ENFSI	European Network of Forensic Science Institutes
EU	European Union
EUROPOL	European Union Agency for Law Enforcement Cooperation
EWA	Early Warning Advisory
EWS	Early Warning System

ICE	International Collaborative Exercises Programme
IQAP	International Quality Assurance Programme
NEWS	National Early Warning System
NIDA	National Institute on Drug Abuse
NPS	New Psychoactive Substances
OEDA	Spanish Observatory on Drugs & Addictions
OFDT	French Observatory on Drugs & Drug Addiction
OID	Inter-American Observatory on Drugs
OND	National Observatory on Drugs
REITOX	Réseau Européen d'Information sur les Drogues et les Toxicomanies <i>European Information Network on Drugs and Drug Addiction</i>
SAPR	Sistema de Alerta Precoz y Respuesta <i>Early Warning and Rapid Response System</i>
SMART	Synthetics Monitoring: Analyses, Reporting and Trends Programme
SWGDRUG	Scientific Working Group for the Analysis of Seized Drugs
UNODC	United Nations Office on Drugs and Crime
UNGASS	Special Session of the United Nations General Assembly on the World Drug Problem

GLOSSARY

Adulterants: Pharmacologically active substances with properties similar to the drug meant to offset the potency lost in dilution.

Contaminants: Foreign substances that may appear during the synthesis, manufacture and processing of the drug, which make the substance impure. Contaminants or impurities, are commonly solvents, acids or bases, plant-derived alkaloids, or synthesized compounds.

Diluents: An inert or structurally different compound added to the drug to increase its bulk and reduce its active component. Typically, diluents appear similar to the drug itself, in terms of color, consistency, taste (e.g., blending cocaine with sugars, talc, or mannitol).

Early Warning Systems: A multi-disciplined interagency network formed by key stakeholders that generate and exchange information to: a) identify early, events that pose a threat to public health in the area of new psychotropic substances or emerging drug phenomena, b) evaluate the risks related to their usage and c) send out early warnings for the design of effective responses.

Emerging Drug Phenomena: Events linked to known substances in a country that demonstrate disruptive patterns in regular consumption, changes in the current chemical composition (e.g., new

adulterants, contaminants or diluent detected), behavioural changes, or changing consumption patterns which could potentially lead to new risks for public health¹.

New Psychoactive Substances (NPS): These are a group of psychoactive substances, the majority of which are synthetic in origin, but can also be vegetable in origin, medical or veterinary products that will not be found in the list of controlled substances according to United Nations' international conventions, and which can pose a threat to public health. They can be new designer drugs or substances synthesized long ago that emulate or even surpass the effects of substances already controlled. They are commonly marketed as "legal highs", as chemical research products, as food or as medicinal supplements².

Threat: An event or a phenomenon associated with the use of psychoactive substances that may cause harm to a population.

Warning: A summary of structured information based on a threat in the public health arena associated with New Psychoactive Substances collated and submitted by the Early Warning System to specific recipients to prevent negative impacts on public health.

1. Annex 8 includes extensive information on emerging drugs.

2. Annex 8 includes extensive information on new psychoactive substances.

OVERVIEW

This manual has been developed under the framework of the Cooperation Programme between Latin America, the Caribbean and the European Union on Drugs Policies (COPOLAD II), specifically Component 1: Institutional Strengthening of National Drug Observatories (NDOs), Activity 1.3: “to promote and facilitate the establishment of Early Warning Systems (EWSs) in CELAC Member States.”

This activity forms part of the objective to promote and strengthen agreements for information exchange between National Drug Councils, National Drug Observatories and other key institutions in CELAC Member States to facilitate the flow of information to effectively confront new threats related to the drug phenomenon. Under this framework, the objective is to strengthen functioning EWSs, as well as to promote and support the implementation of these systems in those countries that request such support.

Considering that very few CELAC countries have implemented EWSs, the methodology proposed in this manual is specially oriented towards the contribution of **fundamentals and a basis for the implementation of EWSs** and their management as a critical tool that complements and adds value to the existing information within National Drug Observatories. At the same time, it responds to the immediate needs of having real-time evidence on the most dynamic elements of the drug phenomenon, seeking to improve the res-

ponse capacity and the intervention of institutions and key players in a context where complexity and dynamism interplay daily among professionals involved in this area of work.

One key philosophy that this manual subscribes to is that the coordination of EWSs should fall within the functions of the National Drug Observatories, notwithstanding their diverseness in size, structure, and approach across the region. It is, therefore, necessary to consider that on one hand, as stated by the CICAD/OAS, there is no single drug problem in the Hemisphere, but several in the region and within each country, while on the other, Latin American and Caribbean countries have diverse political, legal and administrative contexts, which in part explain the heterogeneity of their National Drug Observatories. In this way, implementation of an EWS coordinated by the National Drug Observatory will be conditioned to some extent by the peculiar aspects of each entity.

An EWS is defined in this manual as an inter-institutional, multidisciplinary network comprised of key stakeholders that generate and exchange information for a) the early detection of events that may pose a threat to public health and which result from the appearance of NPS other or emerging drug phenomena, b) the assessment of risks related to the presence of those substances and c) the issuance of early warnings to produce effective, real-time responses.

It is important to distinguish between an EWS and a national drug information network (DIN). A DIN is also multidisciplinary network comprised of key stakeholders that generate and exchange information, and may include many of the same stakeholders as the EWS; however, a DIN is focused on the long-term monitoring of the drug situation, with a strong basis in the collection of scientific evidence. The ultimate goal of a DIN is to monitor drug issues over the long-term to inform drug policy, while the ultimate goal of an EWS is to provide rapid information that can result in immediate responses to reduce risk to public health. Ideally, a national EWS will be

built using the infrastructure already available from the DIN but will focus on the key information sources that permit early detection and response to emerging threats.

This manual is based on the document *Creation of a National Drug Observatory: A Joint Manual*, published by the European Monitoring Center for Drugs and Drug Addiction (EMCDDA) in collaboration with the Inter-American Drug Abuse Control Commission of the Organization of American States (CICAD/OAS), since much of the advice provided in the EMCDDA's¹ document can be applied to the creation of an EWS. It also takes into consideration the manual for the implementation of the Early Warning Systems of the European Union (EU/EWS, European Union Early Warning System, EMCDDA-Europol, 2007). This manual establishes the scope, elements and key reporting tools. Finally, it includes critical components of the manual entitled *Emerging Drug Phenomena. A European Manual on the Early Information Function for Emerging Drug Phenomena* coordinated by the French Observatory of Drugs and Drug Addiction (OFDT, 2003).

Accordingly, the purpose of this manual is to offer a generic EWS model that each country can adapt to its unique situation and specific needs. We believe that ultimately, EWSs will become useful, reliable, effective, and efficient instruments for stakeholders in the network, and those involved in the development of drug policy as well. This document provides a description of the components of the EWS, its function, as well as a guide for its implementation or strengthening as appropriate. It is presented as a flexible model for guidance without pretending to be unique.

The manual has three chapters, bibliographical references, and nine annexes. The first chapter includes the definition of the EWS and

1. http://www.emcdda.europa.eu/system/files/publications/581/EMCDDA-NDO-handbook-es_237119.pdf

its objectives, a description of its functions, basic characteristics, requirements, operating mechanisms, and other key areas. The second chapter outlines the steps for adequate implementation of EWSs in those countries that do not yet have a system, considering the different contexts that may exist among them. Key questions for the implementation and identification of stakeholders comprise the core elements of this chapter. Finally, the third chapter presents recommendations for the management of EWSs, which include a description of the main data to be handled by the EWS; the instruments for collection and management of data, the flow of information, the platform for information exchange and tools for internal communication and warnings.

Nine annexes are included in the manual containing suggestions for instruments (spreadsheets, record sheets, and communication tools, etc.) for implementation of the EWS and suggestions to keep it operational. These are referenced in corresponding chapters; documents on the current situation of new psychoactive substances across the world and a brief description of existing Early Warning Systems.

GENERAL ASPECTS OF EARLY WARNING SYSTEMS (EWSs)

1.1. Definition, Mission and Objectives

The **mission** of an EWS is to support public health and security. The **goal** of the EWS is to provide a rapid response to the adverse changes in the drug phenomenon to minimize the risks associated with it.

MISSION

The care of public health and security for the optimal wellbeing of society

GOAL

To deliver early warnings regarding changes in the drug problem and in order to develop rapid, effective responses and minimize risks.

GENERAL OBJECTIVE

Maintain a surveillance system through the use of information from sources such as epidemiology, public health, security, as well as data on NPS, and other emerging drug phenomena to support the development of rapid interventions.

The **general objective** of EWSs is to maintain a surveillance system that includes information from multiple sources such as, epidemiology, public health, security, as well as data on new psychoactive substances (NPS), and other emerging drug phenomena to support the development of rapid interventions.

Among the specific objectives suggested for an EWS on drugs, are:

- To provide rapid and accurate information on the NPS situation and the other emerging drug phenomena in the drug market.
- To systematically monitor the availability and the consumption of NPS and other emerging drug phenomena (for example, new consumption patterns, undisclosed or unusual events linked to drug consumption, significant quantities seized, adverse effects related to drugs or to their adulterants, etc.).
- To provide up-to-date information on the chemical composition analyse (qualitative and quantitative, including identification of the main adulterants and diluents¹), NPS and other "traditional" substances already known in the market for which a change in the chemical composition may be suspected that might entail health risks.
- To rapidly evaluate the risks and impacts associated with the use of NPS or emerging drug phenomena on the health of users (pharmacological, clinical, and toxicological information).
- To quickly disseminate information on new NPS and on emerging drug phenomena among professionals and eventually among the population at risk.
- Depending on the mandate of the EWS in each country, to inform policymakers in the drug arena about NPS and the emerging drug phenomena.

1. To facilitate reading, we have used the expression "chemical composition or categorization" throughout the document instead of "qualitative and quantitative chemical composition including the identification of key adulterants and diluents".

Results & Contributions expected from the Early Warning System:

- Expansive knowledge on NPS and on the emerging drug phenomena in the country.
- Strengthened National Drug Information Systems in countries.
- Contributions towards epidemiological surveillance achieved by National Drug Councils.
- Strengthened drug policy with the greatest efficiency and speed of actions, producing relevant information and timely interventions in the area of drug demand and drug supply reduction.
- Improvement in the control of NPSs using legal methods.

Operationally, the Early Warning System is an institutional network with key stakeholders who are directly or indirectly linked to drug control and who are coordinated preferably by a national drug council with a specific purpose. The institutional network is understood as the collaboration and interaction between institutions and different key stakeholders, where each one contributes, according to their functions and expertise, to the phenomenon under study and observation, **but driven by the specific purpose that defines the EWS**. Forming a network makes it possible to exchange information and to establish and build joint projects and activities. One example of this is the contribution offered to control, inspection and regulatory bodies with information on the identification of new psychoactive substances, including toxicological profiles and adulterants that are sometimes more dangerous than the main substance. In this way, the identification of a new substance, whether a adulterants or a chemical precursor, can activate mechanisms for control and regulation, using various legislative and regulatory resources that, varying from country to country, aim to reduce production and trafficking of substances.



Dimensions of analysis for EWS

In order for the EWS to capture the salient aspects of the phenomenon of new psychoactive substances and emerging drugs, it must include the following areas for analysis:

- Chemical composition of substances using seized samples and/or samples collected from users or buyers on the Internet.
- Analyses of clinical cases and biological samples associated with the adverse effects from deaths and intoxication, and the results from autopsies, etc.

Apart from the above-mentioned components, and considering as an example, the definition of the "Early Warning and Response System" (EWRS) for the notification of warnings related to serious cross-border threats to health², the following operational definition of EWSs for drugs has been established:

Operational framework



An EWS is a multidisciplinary interagency network managed by key stakeholders who generate and exchange information with the aim of: a) identifying early NPS, other emerging substances, and other drug-related events that pose a threat to public health, b) evaluating the risks related to their use and c) sending out rapid warnings for the design of effective responses.

2. At the level of the European Union, it has been established that the issuance of warnings allows the Commission and national authorities to remain in constant communication with the aim of alerting, assessing risks to public health and identifying measures that may be necessary to protect it (Decision No. 1082/2013/EU of the European Parliament and of the Council on 22 October, 2013 on serious trans-border threats to health. Available at: <https://eur-lex.europa.eu/legal>)

According to the mission and general proposed objective of the EWS, its key functions consist of:

- Generating information exchange between stakeholders involved in the system, guaranteeing a constant flow of information (once the data collection forms are agreed) on NPS and on emerging drug phenomena from a wide variety of sources and institutions.
- Establishing a responsive yet flexible system in anticipation of a new event that aims to generate a rapid exchange and dissemination of information, enabling the development of responses and timely interventions for potential threats to public health.
- Systematizing data collection and validating the information compiled on NPS and on emerging drug phenomena.
- Disseminating warnings to the network and to other relevant stakeholders, making them public (after careful consideration of possible undesired negative impacts) as a key result of the EWS to minimize risks associated with the use of NPS and other drugs.
- Monitoring in the medium and long term, the phenomena reported to the system to determine its development and ongoing trends.
- Producing reports and other documents designed specifically for the recipients to whom it is intended to communicate different events and other relevant issues.

Other suggested functions:

- To support international mechanisms on data collection of NPS and on drugs in general lead by agencies and programmes such as the United Nations Office on Drugs and Crime (UNODC), CICAD/OAS, COPOLAD, EMCDDA, etc. by communicating national warnings or other information considered relevant, thus contributing to the national, regional, international and global understanding of the phenomenon.

- To promote and support research projects that provide knowledge and information to the EWS on a particular subject matter to strengthen scientific evidence.
- To promote conferences and scientific professional meetings on the topic of NPSs and emerging drug phenomena to generate a basis for conceptual exchange and empirical information to ensure a joint understanding of the situation.
- To promote the training of network members in their respective areas of competence and activities, making available timely and credible information about events linked to the emerging drug phenomenon at the national and international level.

1.2. Basic Principles

- **The establishment of a multidisciplinary network of stakeholders and institutions** that represent important sources of information on the drug phenomenon, and who jointly guarantee the provision of information from different perspectives.
- Adequate and precise **adaptation of the system to national** and local needs and situations in the area of the emerging drug phenomenon.
- **A proactive and responsive network** to maintain the system in permanent operation. A system with a low level of activity risks stagnation and failure. In this respect, one of the essential tasks is to ensure the appropriate involvement of the EWS's members to maintain constant levels of participation.
- **The exchange and usefulness of information** among members and the coordination of the EWS as one of its central pillars. The EWS should be seen as a useful tool for all involved.
- **Respect for the mandate and competencies of the participating agencies** in the network.

- **Relevance of the information** circulating in the system according to the objectives that it has set. Handling information that is irrelevant or inconsistent with the objectives of the EWS can contribute to confusion and malfunction.
- **Supporting scientific evidence**, especially focused on chemical composition and description of harm related to the use of specific substances, as well as those coming from other disciplines (epidemiology, social sciences, biology, preclinical studies, etc.).
- The information circulating in the EWS must be subject to **validation and quality control processes** that guarantee the development of reliable and evidence-based communication products.
- **Protection and responsible treatment** of information circulating in the system, which by definition, is sensitive.
- **The availability and adequacy of human resources**, infrastructure, etc. that guarantee optimal functioning of the system.
- **Good practices based on ethics, respect for human rights, confidentiality, and professional transparency** both in the exchange of information and in its dissemination to network members, and to those outside of the network.

1.3. Best Practices

- **The existence of a legal framework** which supports the establishment and operation of an EWS. In many cases, regulations can often be a tool to safeguard (good) compliance with certain procedures, mechanisms, or actions.

In the case of the EWS, it has been noted that legal frameworks established in other countries and regions provide for Early Warning Systems, their operation, coverage, management, institutional integration, among other areas. The existence of these legal

frameworks has a direct positive impact on systems, as they guarantee functionality and permanence over time, as well as provide systematic coordination with some measure of compulsion at certain levels or within activities.

- **The existence of standardized protocols and procedures.** Protocols are those guidelines that meet the criteria or rules by which certain actions, outputs, or processes must be activated. In the case of EWSs, protocols may exist covering, for example, how the flow of information is to be performed or mechanisms established for the treatment, validation and dissemination of information circulating in the system. There may also be protocols that provide an account of the procedures to incorporate participants into the system (if not already established in the regulatory frameworks).

These tools seek to standardize and systematize the responses or actions to follow within the system, establishing clear mechanisms for the coordination of the system as well as for its participants. The availability of protocols can facilitate the proper functioning of the system by making it more efficient. For example, the joint EMCDDA and Europol handbook (EMCDDA-Europol, 2007) provides guidelines for the implementation of the EU's EWS, information flows and specific tools for the exchange of information on NPSs in the European Union. Some of the tools that you will read about later in this manual are adaptations of these.

- **Availability of specific resources for the Early Warning System.** As in all areas, the chances of survival or continuity of projects or initiatives may be questioned if specific resources are not available for their operation.

The EWS is not foreign to this, **and while it can function without exclusive resources, its effectiveness and sustainability would be placed at risk.**



A Case Study

The European Union's Early Warning System (EU EWS) was established in 1997 by the EMCDDA and Europol in collaboration with Member States of the European Union (EU) under the Joint Action of 16 June, 1997 on information exchange, risk assessment and control of new synthetic drugs. Each EU Member State articulates its national system according to its internal organization. Subsequently, Decision 2005/387/JHA of the Council of the European Union of 10 May, 2005 on the exchange of information, the risk assessment and control of NPSs replaced the Joint Action of 16 June 1997 on information exchange, risk assessment and control of new synthetic drugs. Recently, a new reference regulation was adopted by the European Parliament and the Council of the European Union on 15 November, 2017 and published in the Official Journal of the European Union on 21 November, 2017. The new legislation consists of Regulation (EU) 2017/2101 of the European Parliament and of the Council of 15 November, 2017 amending Regulation (EC) No. 1920/2006 regarding information exchange, the rapid warning system and the risk assessment procedure for NPSs and the Directive (EU) 2017/2103 of the European Parliament and of the Council of 15 November, 2017 amending Council Framework Decision 2004/757/JHA to include NPSs in the definition of drugs and repealing Decision 2005/387/JHA.

On the one hand, support is required for material resources (financial and construction) that support Early Warning System activities (communication, information exchange, etc.). On the other hand, it is essential to have professionals and technical staff who have sufficient time and training to perform EWS tasks.

- **Feedback from the system.** The establishment of different mechanisms that enable system feedback, systematic evaluation and improvement of the system over time (World Meteorological Organization, 2011).

1.4. Sensitive Characteristics on the Information Populating the System

The information which populates the system must, by definition, be treated as sensitive even though it forms part of the internal management of the institutions and key stakeholders who upload it in the system.

In addition, some data may require triangulation with information from other areas to corroborate or complement them. In this regard, the EWS should ensure the utmost confidentiality of the information it handles, and this, therefore, means that access to the system should be managed with security measures to provide confidence to its members. In these cases, data and information circulated must reference the institutions and stakeholders; the mode of dissemination, and how they should be referenced or quoted, should be agreed by them.

1.5. Coverage/Reach

While EWSs may vary in scope in terms of their territorial coverage (local, national, regional, international), systems of national scope

need to be highlighted due to "their potential to provide evidence, the possibility of strengthening the response of health officials, and to influence the consolidation of public policies in this regard" (COPOLAD II, 2017, page 51).

Therefore, **the objective of this manual is to support the basic principles for the establishment of an Early Warning System at the national level.**

1.6. Administration and Institutional Affiliation

The EWS assumes different levels of action that include the systematic collection and organization of information, as well as its processing and analysis, and, finally, rapid dissemination of information where appropriate. The EWS must be inter-institutional and interdisciplinary to function effectively and efficiently.

The key institutions and stakeholders that comprise the network are the operational members of the EWS. They are responsible for providing relevant and rapid information on specific events according to the objectives set for the system. At the same time, they will benefit from the information provided by other institutions, enabling them to keep up-to-date on a given subject.

Key institutions and partners included in the EWS include those linked to drug supply control since much of the information will come from drug seizures. Laboratories that perform chemical analyses of drugs must be included e.g. forensic institutes, universities, government agencies, and others) for identification of substances reported in the system. Health and treatment centres, especially primary care, are also important because of their close interaction with drug users and their potential as a source of clinical and toxicological information, and as transmitters and generators of knowledge and good practices for the health care of drug users.

Therefore, an EWS must play a coordinating role ensure and encourage the participation of stakeholders. At the same time, the EWS must be responsible for the organization, validation, and consolidation of information circulating in the EWS, and analyse the information, incorporating more variables, where possible.

The person responsible for coordinating the system must ensure that each function is fulfilled and safeguarded, that the system is organized, particularly the information flow that will be administered and guided by this individual's role. **In this way, it is understood that National Drug Observatories (NDOs) can play a pivotal role in EWSs if we consider their functions and the “know how” that they possess towards a holistic analysis of the drug phenomenon.**

According to the EMCDDA-CICAD/OAS manual, "a National Drug Observatory (NDO) is an organization that provides its country with factual, objective, reliable and comparable information on drugs, drug addiction and its consequences. (...) The three essential functions of a NDO are: data collection and monitoring; analysis and interpretation of the information collected; reporting and dissemination of results" (EMCDDA-CICAD/OAS, 2010, page 21).

To do this, National Drug Observatories need to be part of a broader system that involves:

- A concerted and balanced national drug coordinating mechanism which oversees the role of the various partners involved in implementing a national drug strategy.
- A national drug information network, integrating general and specialized sources of advanced technical knowledge and information, as well as systematic surveillance programmes and *ad hoc* studies on target groups. (EMCDDA-CICAD/OAS, 2010, page 22).

In this way, it is evident that the role of National Drug Observatories is intimately linked to the development and cooperation of other institutions that provide relevant information. The National Drug Observatory will be responsible for gathering information and monitoring it, ensuring its continuous quality improvement based on technical cooperation and revision.

It is also the task of a National Drug Observatory to analyse information, interpret it, and produce new knowledge. On the other hand, it will carry out periodic studies and additional or supplementary studies and will prepare special reports. To achieve these objectives, NDOs use different methodological tools, many of which meet international standards, endorsed by experts and supra-national bodies. These tools include epidemiological studies using surveys on the general population and upper secondary school students.

Surveys are also carried out on university students or other specific populations (patients in drug treatment, detainees, etc.); also surveys in emergency or epidemiological settings, studies using special methodologies such as *Respondent Driving Sampling*, cost studies, chemical composition of substances, cultivated areas, wastewater studies, drug trafficking patterns and related offenses, studies on sustainable development projects, qualitative research, among others.

Considering that EWSs contain specific tools to monitor the phenomenon of NPS and emerging drug trends, it is critical that management relies on an entity such as the National Drug Observatory. They bring together the necessary expertise in coordination and cooperation with other institutions and experts in the field, collecting and analyzing the information they provide. In addition, this capacity and expertise enables them to add value to the outputs produced by the EWS.

The systematic roll-out of key studies discussed above, as well as other studies, would also support the work of the EWS by providing the network with key inputs from scientific research. On the other hand, it is essential for a National Drug Observatory to have first-hand information provided by an EWS since it will enrich understanding of the drug phenomenon. Therefore, as the COPOLAD Programme postulates, EWSs are tools that increase the potential of NDOs, strengthening them institutionally, and through the knowledge that they produce.

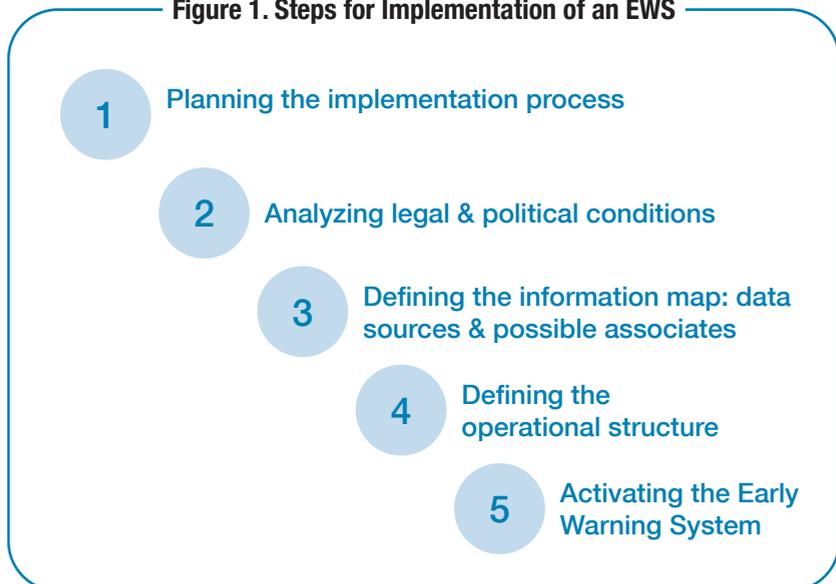
All these reasons justify the need for the EWS to be placed within the national drug observatory, and considered among planning indicators for monitoring, and to be placed in specific budget allocations.

Various international experiences demonstrate thus far, that management & administration of EWSs may fall on different agencies. However, given the above, it is suggested that management of the EWS remain under the remit of the country's National Drug Observatory.

CREATING AN EARLY WARNING SYSTEM

The current chapter aims to provide guidance on how to operationalize an EWS, and to provide a framework for its implementation through five specific steps, described below, considering that each country will develop its own model, according to its particular context.

Figure 1. Steps for Implementation of an EWS

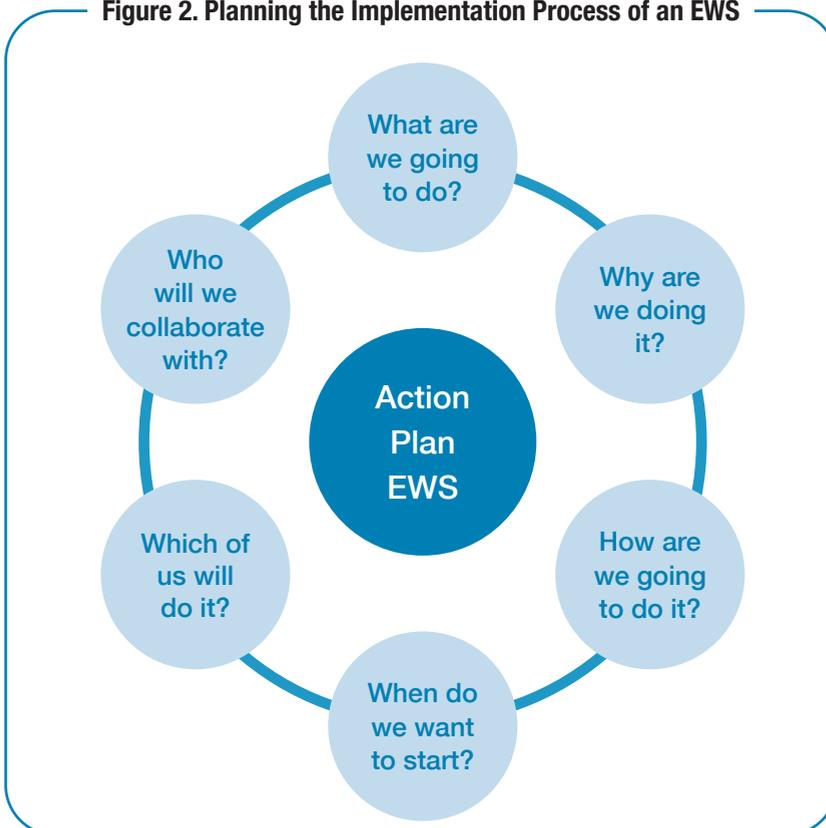


The suggested steps follow a plan of action, however, it is not necessary to cover them successively, but there are critical times when they must be carried out in accordance with particular conditions.

2.1. First Step. Planning the Implementation Process

One fundamental condition of initiating the planning process is to define the function, objectives, concepts and other central elements of an EWS as described in the previous chapter.

Figure 2. Planning the Implementation Process of an EWS



Planning entails the range of activities that must be followed to operationalize the EWS and defining key questions, as presented in figure 2:

What? Why? How? When? Who? and with Whom?

It is also important to understand the context of implementing an EWS, that is to say, being immersed among the threats and trends of the NPS and emerging drug phenomena in a country, both regionally and internationally. It is also important to understand the identification process for NPSs, how the information is disseminated, and which stakeholders have participated in these processes.

Given the mandate and experience of Observatories, an understanding of drug problems in general is facilitated, and the institutional architecture linked to a given subject is known.

Getting to know the institutions and stakeholders is central to the design of the EWS.

It is necessary to identify the experts responsible for the leadership of the EWS in the National Drug Observatory's team. Other resources to consider are technology (IT platform to administer the information in the EWS), and finances (if the plan is to contract staff exclusively for the EWS or in the short-term for meetings, events, and to print documents, etc.).

No doubt that with the human, technological and financial resources within the National Drug Observatory, it is possible and highly feasible to initiate implementation of the EWS, which can be strengthened after the process begins.

What to do if a country does not have information on new psychoactive substances and emerging drug phenomena?

In some cases, it is possible that a country does not rely on key information previously described; in this case it is advised to:

1. Not abandon the initiative to establish an EWS because of a lack of specific/key information. While it is impossible to establish an EWS without information, the absence of key data should not be an impediment to its establishment.

2. Consider the possibility of analyzing and incorporating other available data in the country that would help to activate the EWS. It is possible that other data exists in the



country which would bring knowledge of the phenomenon of NPS and emerging drugs that enable the EWS to be developed. In fact, the first data to be considered should be those coming from interdiction efforts (Supply Control). Other data to bear in mind are those coming from drug users themselves. The latter should be one of the primary sources of information given that they are easily accessed (for example: treatment centres, user forums, among others).

3. Bear in mind that the initiative to establish an EWS and the interagency exchange, requires conditions that are conducive to promoting information that may not yet be available. The encounter between multiple institutions can serve to raise awareness about the issue of NPS and the emerging drug phenomenon and promote cooperation and cohesion so that information that is not yet available is produced and systematized.

Recommended Activities:



As part of the planning process for implementation of the EWS, prepare a document containing the following components:

Justification

Why is an Early Warning System necessary? What is the real situation on NPS and emerging drug phenomena in a country, regionally and internationally?

Description of the Problem

How are we actually managing the situation on NPS and emerging drug phenomena? What are the difficulties that we face and how could an EWS help to overcome this problem?

Explanation or presentation on the EWS

Focusing on its goals and objectives as well as its results and expected outputs.

Objective

What purpose will the EWS serve? What contribution do we expect from the EWS in terms of public health, drug control, and other areas?

Description

National reference point, description of the relevant information and advantages at the national level.

Resources involved



- An analysis of the human, technical and financial resources required.
- Team in charge: Who will be responsible for leading the implementation of an EWS?

Please consult:

- ➔ Annex 1: Road Map
- ➔ Annex 2: Plan of Action (what? how? when? who?/
Objectives, Activities, Leadership, outputs, dates)

2.2. Second Step. Analysis of the Political and Legal Framework

In the process of preparing for an EWS, it is necessary to examine multiple areas and to engage in activities that promote its operation. Of note is the examination of the political, legal, technical and institutional framework, and to give consideration to the institutional strengths and weaknesses.

Political Framework

Like any initiative, the decision to implement an EWS should receive political approval from the relevant authorities which will be embodied in protocols of action, working agreements between the different institutions, departments and/or ministries involved. If this does not occur, it would be advisable to conduct sensitization and information sessions among political institutions and decision-makers

on the threat posed by NPSs and the emerging drug phenomenon, as well as the role of an EWS as it impacts them.

Legal Framework

There are guidelines given by international organizations that highlight the need to monitor and track NPSs through the EWS, among other activities, and are centered on improving the response to challenges posed by a proliferation of these substances. In fact, the United Nations Commission on Narcotic Drugs has adopted several resolutions related to the problem of NPSs, and the need to create monitoring systems such as Resolution 48/1, 2005, Resolution 56/4, 2013 and Resolution 58/11, 2015. Meanwhile, within the operational recommendations on the outcome document from the Extraordinary Session of the United Nations General Assembly, 2016 (UNGASS) entitled *Our joint commitment to effectively address and counter the global drug problem*, are issues related to NPSs and the increasing and persistent challenges and threats. Countries committed themselves to strengthen national and international efforts to address the issue and also highlighted the importance of EWSs in identifying trends in NPSs.

Apart from the international legal framework, the development and operation of a national EWS must harmonize with the legal framework on drugs in a given country. To this end, as a preliminary step, it is necessary to compile and analyse regulations in force in a given country regarding the subject matter. This legal framework can be the first output in the process of setting up the EWS, and will serve as a catalyst for the entities linked as partners in the EWS.

For example, key activities of an EWS such as management of data collection of drug samples, their chain of custody, receipt at the lab, analysis of chemical composition and communication of these results, must all be considered in keeping with the competencies, au-

thority and functions of the institutions involved (mainly health and supply reduction) from the point of view of lab analysis and the protocols established by each country.

When it relates to information emerging from the health or forensic sectors related to people, for example, emergency drug cases, deaths, etc., it is important to define how this information will be registered in the EWS and if there is any restriction to public disclosure. For example, there could be restrictions tied to the norms that protect personal data.

In particular, we need to consider that each country has its own legal and procedural framework for the analysis of seized substances, and that it should be investigated whether substances that do not emerge from seizures can be analysed. As an example, civil society organizations might have information or access to drugs from users that could eventually be sent to forensic labs for analysis. Therefore, for the EWS to function, it is appropriate to compile information related to all these identified mechanisms and to develop a document linking them, which will be relevant to the EWS.

In summary, it is necessary to review the laws or norms (of all types) on drugs, as well as the functions, competencies, procedures, and protocols of the authorities and forensic labs and drug analysis in each country. In many cases, drug legislation will define the boundaries of the EWS operation.

Suggested Activities



It is recommended that the format at Annex 3 be completed by identifying the Law or Standard related to the activity, specifying if there is any impediment and how it could be resolved.



Questions for Guidance

- Can the institutions that have information relative to NPSs or to the emerging drug phenomena, share it with the EWS? (seizures, chemical composition, health events such as intoxication, overdoses, and deaths?)
- What are the legal steps and procedures through which seized substances are analysed for their chemical content?
- Can labs submit the results of the chemical composition of substances to the EWS?
- Can labs analyse substances that do not come from seizures, if requested by the EWS? In this case, which institution can transport the substance from where it was found to the lab?
- Which mechanism is necessary to formalize the creation of an EWS?

Analysis of the legal aspects, as described, can also indicate if it is necessary to issue standards for the creation of an EWS or to define what type of document is required to endorse or formalize the operation of the system. It is particularly important that the EWS has formal status through a mechanism that each country considers appropriate. This implies, in this instance, defining the functions of the system, competence, stakeholders involved, among other key areas, which ultimately represent legal recognition of its existence and operation.

2.3. Third Step. Information Map: Identification of Data Sources and Possible Members

The EWS is a network of information exchange which includes institutions and stakeholders who are linked to drug supply and drug demand reduction in each country or who may have some related competency with specific objectives.

However, identifying these institutions and stakeholders is a necessary step for implementation.

This chapter proposes to map information by identifying sources and potential members, initially listing the information required, the institutions, areas, and relevant contacts.

Among the stakeholders, we need to consider forensic laboratories that are charged with identifying or determining the chemical composition of seized substances in each country; they are a pivotal source in identifying NPSs and emerging drugs.

Similarly, institutions that offer health care or that have information on adverse health events associated with drug consumption can be important sources to detect the presence of NPSs or emerging drugs, especially when they are successful in identifying the causative drug through biological sample analysis.

The EMCDDA-CICAD/OAS manual makes the following suggestions for the creation of an information map:

- 1) Identify the main counterparts, 2) convey the objectives to them, 3) organize a meeting to exchange information.
- Send an explanatory document so that your contact persons can convene meetings with experts using potential sources of information.

- Convene joint meetings with various experts and agency representatives; this will help you to gather more information and will encourage people to get to know each other.
- If actual meetings are not possible (size of the country, budgetary restrictions), use video-conferencing or other activities (for example, a virtual conference) attended by experts or managers of institutions which they wish to meet.
- Send the key issues discussed at the meeting to the contact persons, provide your reference information and analyse what happened.
- Send the stakeholders the final version of the information map.
- Keep everyone informed on follow-up actions and results. (EMCDDA-CICAD/OAS, 2010, page 46).

Once the previous mapping has been completed, the identified institutions should be summoned with the aim of effectively becoming part of the EWS. It is important to contact the institutions through visits to each one or to convene a meeting with all stakeholders. It is suggested that prior information be provided on the intended objective, so that stakeholders can be prepared.

One of the key objectives of the first meeting with stakeholders is to make them aware of the threat of NPSs and the emerging drug phenomenon, and the importance of having an EWS. Membership in the EWS and the need to exchange timely information should also be underscored. Each EWS member must be clear about the benefits to be gained from participation in the system.

Apart from the above-mentioned, it is necessary to define with each stakeholder, his contribution to the EWS, that is, the information that he will provide, its formatting requirements, frequency, restrictions or special considerations that the EWS may have.

Priority Data for the EWS

1 Reports on seizures of psychoactive substances. Data on the date and place of seizure, drug seized, presentation, quantity, method of concealment, origin/source, destination, route, photos of the seized drug.

2 Chemical characterization of substances: (NPSs & other psychoactive substances). Analyses carried out in laboratories with appropriate technology and professionals trained to determine the composition of the substance (and concentrations where possible) including the main psychoactive substance but also adulterants, diluents, solvents and other substances.

Identification of patterns of use/administration of NPSs. Consumption patterns of NPSs, setting for use, route of administration, frequency of use, intensity of use, combination with other drugs, etc.

4 Identification of new drug consumption patterns, "traditional" or drugs already known on the local market. Different presentations to those already known, new routes of administration, new effects of drugs, new context of consumption.

5 Report of clinical cases of intoxication/overdoses of NPSs or substances already known or adulterants.

Expert reports from the health sector where the reason for the consultation is described, the situation in which the person is admitted to the health centre, symptoms that he/she presents, consumption of the substance (depending on the result of analysis or at least by the user's own declaration), the context of consumption, clinical and paraclinical studies carried out and their respective results, diagnosis, medical indication (with or without pharmacology), evolution, and discharge information. Data on sex and age. This information is anonymous.

6 Forensic Analysis Results of Death due to Drugs.

7 **Toxicological Information on Autopsies.** Report of forensic analysis (post mortem examination) where the presence of psychoactive substances in a body is identified, even if death has not been directly caused by their use.

8 Report on the harmful health effects of the use of psychoactive substances and/or contaminants present in these substances. Information that reports on the toxicological and clinical impact from the use of NPSs on people's health, a substance already known on the local market or an adulterant.

One key aspect of the EWS's success is to strengthen institutional ties permanently, to provide information exchange, to convene regular meetings and to maintain active communication by various means with all the institutions in the network.

On this matter, it is therefore essential to achieve two objectives:

- a. Identify and meet with the person who will act as the institutional representative or focal point. These focal points will represent the institution in the EWS and will be required to actively participate.
- b. Inform the institutions and those concerned, in particular, of the purpose of their participation in the system, as well as the information required of their institution. To this end, it is necessary to agree on the details for providing information, and to train the institutional focal points on the system's operation and its general tasks.

At this stage, management of the EWS, the coordinating mechanism and the role of the members should be very clear.

The coordination unit of the system (National Drug Observatory) will gather all the information provided by members and will proceed to administer it.



Questions for Guidance

What information is required and which institutions and/or stakeholders have access to or produces this information or has related competence with the detection of NPS and the emerging drug phenomenon?

It is important to consider the following in relation to the institutions and stakeholders¹:

National Drug Councils

Lead agencies of national drug policy need to be included in the EWS since they will be able to provide information related to Drug Demand and Drug Supply Reduction.

Supply Control Forces: Ministry of the Interior, Ministry of Security, National/Local Police, National Customs, other Supervisory and Interdiction Authorities

Police forces and specialized units in the fight against drug trafficking can obtain drugs and various information on illegal markets for psychoactive substances from seizures, arrests, detentions and from various operations that they conduct. Depending on their jurisdiction, some forces may or may not act; however, the information is of great relevance in all cases. For example, Customs can provide the EWS with information on shipments of seized or suspected substances. This is particularly relevant in the case of NPSs and the knowledge that can be gained on trafficking, concealment mechanisms, origin, destination of the substance, criminal networks, etc.

Ministry of Legal Affairs/Prosecutors/Courts

Given their mandate which is fundamentally linked to the dispensation of justice and crime reduction, they can provide the EWS with information on judicial cases.

1. The following list was developed using the general criteria proposed in the *European Manual on Early Information Systems on the Emerging Drug Phenomenon* (EMCDDA, 2003).

Forensic/Crime/Toxicological/Clinical Laboratories

They conduct analyses of body fluids, biological samples (blood, urine, etc.) or on drug samples (seizures or substances provided by drug users) and therefore obtain information on the identification of substances, physical, chemical and pharmacological characteristics.

They can provide information on both the composition (which substance does it contain?) and the concentration of the active substance (how much of “x” substance does it contain?). They may also disclose the main active component (main psychoactive substance) and the presence of adulterants and thinners.

Which **institutions or stakeholders** conduct chemical characterization of substances and/or toxicological analysis?

- Identify labs that have the capacity to conduct chemical characterization or biological matrix analysis so that they may participate in the EWS.
- Remember that chemical composition of substances and analysis of biological matrices is the mechanism for identifying psychoactive substances. This constitutes the backbone of an EWS when combined with toxicological analysis. We should identify the institutions conducting such analyses, and investigate the legal and technical feasibility of such laboratories sharing results when identifying a NPS or a substance of interest to the EWS, and/or perform drug analyses from sources other than seizures.

Once you have made contact with the laboratories, you can also conduct a personal interview to establish and document the following key conditions: 1. General information on the laboratory and its human resources, 2. Facility, 3. Types of samples analysed, 4. Instruments used and technical equipment available and 5. Quality Control. To this end, the use of the Forensic Laboratory Characte-

rization Form is recommended for those participating in the EWS . It is important to inquire about the ability to detect NPSs, as well as equipment and techniques available in laboratories involved in the identification of substances, availability of standards and participation in inter-laboratory projects coordinated by UNODC, among other areas.



Annex 4. Categorization Form for Forensic Labs

Ministry of Health/Health Care Services (including Hospital Emergency Centres/Specialized Mental Health Services)

This includes all levels of health care. Through direct contact with drug users and through the analysis and treatment of clinical cases of drug intoxication (NPSs or emerging drugs), these services can provide very valuable information to the EWS. These entities can report these cases when they are confirmed, and to report their characteristics and evolution.

Specialized Health Care and Treatment for Drug Use/Drug Detoxification Centres

Similar to the aforementioned general services, it is important to make special mention of centres specializing in the care of drug users due to their direct contact with psychoactive substance users and possibly knowing the substances through them, accessibility and trafficking, quality, price, market innovations and new patterns of use. In addition, toxicology services can provide knowledge on the effects, toxicity, manifestations, and procedural protocols in cases where NPSs or emerging drugs are used. It is important that diverse health care arrangements be included in this group, that is, those with a defined institutional structure and those with low threshold or community-based arrangements.

Low Threshold Risk and Harm Reduction Programmes

In this case, we include programmes or mechanisms focused on harm reduction, risk reduction and health promotion. This applies, for example, to supervised consumption rooms, rest areas, syringes and sterile needles for drug injectors, methadone or naloxone distribution programmes, etc. It also includes drug prevention programmes as a direct intervention with drug users from whom we can possibly obtain basic information for the EWS.

This group also includes substance testing programs in the field (for example, those that do analysis at raves) as they can report very valuable information about the chemical composition of substances in a specific market where they can be consumed by any user. These may also include drug supplies obtained at parties or on the "street" for further chemical categorization.

Helplines/Hotlines

These services often constitute the first point of contact with drug users or family members within care, help, or treatment centres. Through these services, users seek help to reduce doubt or problems, such as the need for a specialized treatment centre.

This source has the advantage of providing a full record of those calls and knowing in detail the motive of the call, the profile of the drug user (gender and age, essentially) or caller (if another person calls), the pattern of consumption, the problems that motivate the consultation, and the response provided by the service, as well as the date and time of the call.

Although data collected by this route often lacks chemical confirmation, such calls are very useful in identifying problems related

to drugs, such as outbreaks of poisoning when they are still in their infancy.

Youth Drop-in Centres, Counseling Centres, and Drug Prevention. Civil Society Organizations or Public Agencies

Organizations such as these have the advantage of being the first point of contact with the population, and in particular with drug users in their environment. They can, therefore, obtain important information to monitor NPS and the emerging drug phenomena. In addition to immediate contact, staff working in these centres are often sufficiently trained to record information relevant to the EWS.

Welcome & Reception Centres. Civil Society Organizations or Public Agencies

This group may have equipment or devices designed for the care and reception of specific problems among street persons or refugees in shelters or hostels for other specific populations in critical situations. Teams that work with populations in socially vulnerable conditions where drug use is often very present, can provide information to the system with data on new drug use, new harmful effects or consequences for the health of users, etc.

Academic Research Teams Focused on the Drug Phenomena

These teams can depend on Public & Private Universities, Agencies and Research Institutions that may fall under the remit of different bodies such as universities, Ministry of Education or Culture, among others.

These teams are a direct source of scientific evidence that can be incorporated into the EWS. The academic nuclei that specialize in research on various topics such as chemistry, pharmacology, biological sciences, social sciences, etc. can provide the EWS with relevant information from their research.

Detention Facilities or Other Areas of Criminal Justice

Prison systems are areas of particular interest to monitor the NPS and emerging drug phenomenon. New patterns of consumption and administration can be seen in these locations, new combinations or preparations of substances that arise from devices that inmates, deprived of their liberty, develop to use psychoactive substances in situations of confinement. Within this environment, staff and officers working in these facilities can provide information to the EWS.

Institutions in the Area of Control and Registration of Pharmaceuticals and Food Containing Psychoactive Substances

Such bodies provide information on monitoring and control of medicines and other substances on the market. Depending on the country, they may relate to control regarding the entry of substances into countries, as well as on production levels.

Other Government Organizations

In some cases, it may be necessary for agencies or institutions to provide relevant information to the EWS, for example, the Ministry of Foreign Affairs or other Ministries/Entities involved in science and technology.

Regional Early Warning Systems; Early Warning Systems from Other Countries

National and regional EWSs such as those in the European Union (EU EWS) and the UNODC (Global SMART Programme²) are key sources for any EWS to stay informed about NPSs or emerging drugs at the regional and international level.

International Organizations and Specific Programmes on the Emerging Drug Phenomena and NPS

In addition to international EWSs, supranational agencies and programmes specific to the topic are essential sources of information for any national EWS.

Qualified Informants

Current and former drug users are key informants on the drug phenomena. They know the reality from the inside, being a part of it, clearly identifying its internal logistics, having interacted with the multiple players involved, and the different substances that the market offers. It should be noted that drug users can be contacted in the institutional spaces described above, as well as in virtual environments such as internet fora where they exchange experiences, advice, and opinions on drug use.

Professionals, as well as community workers from different areas, may have contact with drug users or their networks. Organizations linked to family members of drug users or those working in other areas may still have contact with users.

2. Global SMART (Synthetics Monitoring: Analyzes, Reporting and Trends) Programme.

Figure 3. Framework with Priority Data for an EWS and Potential Sources of Information

REPORT ON SEIZURES

- Supply Control Institutions (including different interdiction agencies. For example, the Police
- Customs

CHEMICAL ANALYSIS OF SUBSTANCES

- Labs/Forensic/Toxicological/Clinical departments
- Supply Control Entities
- Office of the Attorney General, Ministry of Justice
- Academic Research Teams

IDENTIFICATION OF USE/ROUTES OF ADMINISTRATION FOR NPSs

- National Drug Observatory
- National Drug Councils
- Health Care Services
- Health Care Services specializing in Drugs
- Programmes/Demand Reduction interventions
- Help Lines
- Support & Advisory Services
- Drug Users
- Detention Centres
- Qualified Informants
- Welcome Centres
- Academic Research Teams

IDENTIFICATION OF NEW CONSUMPTION PATTERNS OF “TRADITIONAL” DRUGS OR DRUGS ALREADY KNOWN ON THE LOCAL MARKET

- National Drug Observatory
- National Drug Councils
- Health Care Services
- Health Care Services specializing in Drugs
- Programmes/Demand Reduction interventions
- Help Lines
- Support & Advisory Services
- Drug Users
- Detention Centres
- Qualified Informants
- Welcome Centres
- Academic Research Teams

REPORTS OF CLINICAL CASES OF INTOXICATION/OVERDOSE OF NPSs, SUBSTANCES ALREADY KNOWN OR CONTAMINANTS

- Health Care Services
- Specialized Health Care
- Help Lines
- Academic Research Teams

REPORTS OF FORENSIC ANALYSIS OF DEATH CAUSED BY DRUG CONSUMPTION

- Labs/Forensic/Toxicological/Clinical Departments

TOXICOLOGICAL INFORMATION ON AUTOPSIES (INDIRECT MORTALITY)

- Labs/Forensic/Toxicological/Clinical Departments

These groups also include teachers, staff working at night in recreational environments, special events with DJs, security staff, promoters, event organizers and producers, etc.

All agencies or stakeholders listed above, as well as others (not included here but potentially relevant) will benefit from their participation in the EWS to the extent that they will receive information of interest from the exchange generated in the system. The information circulated in the EWS will be able to enhance the activities of each participant by providing inputs for the improvement of practices, the development of protocols of action, anticipation of adverse or unwanted events, and some approximation to the dimension of the phenomenon, perhaps less familiar to each of them.

Figure 3 is a framework of priority data for the EWS relative to the data that these sources can provide for a global, dynamic vision of the EWS. It should be clarified that this summary is not intended to exhaust all existing relationships between the data and its sources; on the contrary, it provides the most significant or common links. Other data relevant to the EWS, as well as other relevant sources, and different combinations between the two groups are likely to exist.

2.4. Fourth Step. Defining the Operational Structure of the Early Warning System

Once the stakeholders and roles of each of the institutions have been identified, it is feasible to propose a functional scheme that must subsequently be validated by all those participating in the EWS. Most of the existing EWSs operate within the four phases presented in the diagram below or some adaptation of it.

1. Detection. The system's members must provide information on a new event: e.g., the discovery of new substances in street seizure-

res or samples, associated toxicology, poisoning, or overdose cases forensic or toxicological reports, key informants, general population, if the system has some means of communication to be able to provide information (public complaints), among others.

2. Classification. At this stage, the network is activated as information exchange begins. It is essential to supplement the information with the chemical classification of the substances detected. In the case of poisoning, overdose, and toxicology cases, timely collection of biological samples allowing for confirmation and identification of the substance consumed and its association with symptoms and adverse effects is essential. However, the absence of chemical confirmation should not prevent cases from being tracked. This stage requires communication with other members of the system to contribute information to the assessment of the case or to be informed about it.

A wide range of good practice manuals on substance identification and interpretation of results using different analytical techniques are available in the literature. Among them, the Analytical Manuals of the European Customs³ Laboratory Network, the Analytical Manuals of the European Project, Response³, the recommendations of the Scientific Working Group for the Analysis of Drugs Seized (SWGDRUG⁴), methods recommended by UNODC⁵ and by the European Network of Forensic Science Institutes (ENFSI).

3. https://ec.europa.eu/taxation_customs/sites/taxation/files/nmr_iliade.pdf
https://ec.europa.eu/taxation_customs/sites/taxation/files/ftir_iliade.pdf
https://ec.europa.eu/taxation_customs/sites/taxation/files/gcms_iliade.pdf
https://ec.europa.eu/taxation_customs/sites/taxation/files/hr_iliade.pdf

4. <http://swgdrug.org/Documents/SWGDRUG%20Recommendations%20Version%207-1.pdf>
<http://www.swgdrug.org/ms.htm>

5. UNODC, 2009; UNODC, 2013a; UNODC, 2013b; UNODC, 2015; UNODC, 2017a; UNODC, 2017b.

The validation or confirmation of the event will involve collection and analysis of any relevant data and the triangulation of information from the most diverse sources. In this regard, data collection is a key step, and this process needs to be expanded if the information initially collected is insufficient or unclear. Finally, based on the criteria that the system will offer, the final identification of NPSs or emerging drug phenomena will be carried out. According to the French Monitoring Manual on Drugs and Drug Addiction (OFDT), the criteria to be considered should include its potential dissemination, the health, social, and economic consequences of the phenomenon (OFDT, 2003).

3. Assessment of associated risks. Once the identification of a new event is confirmed, a phase of rapid assessment of the risks associated with this phenomenon will be activated. This will be done through information previously collected, as well as new information and expert knowledge of the system's participants. Coordination plays a key role in this exchange. Information on the substance and event is completed at this stage. It is particularly important to determine the characteristics and risks of the event, and possible categorization of the phenomenon. In Chapter 3 of this manual, "Management and Maintenance of the Early Warning System," content on Risk Assessment is further developed.

4. Issuance of warnings: When the risks of the phenomenon (event) have been assessed by members of the system, a warning is issued. It is important to consider that the communication of risks associated with validated/confirmed phenomena is the *raison d'être* of the EWS; the generation of warnings justifies the existence of the EWS. A warning may be issued to different audiences depending on its content and its scope (target population). It is important to note that the choice of the recipient will determine the type of content to be provided and the strategy and method of dissemination.

Warnings shall be made when:

- There is evidence that consumption of a detected substance can produce serious, adverse effects to health (severe intoxication, risk of death) that require medical assistance or hospitalization.
- There is evidence of unusual and dangerous contaminants present in commonly used psychoactive substances.
- There is evidence of dangerous concentrations of active substances in traditionally-used substances.

2.4.1. Warnings. Definition & Basic Characteristics

The EWS has a key role to play in raising awareness and communicating risks detected and associated with NPS use and emerging drug phenomena. It is therefore essential that these systems have the capacity to inform different stakeholders about situations that pose a threat to public health.

A warning suggests vigilance and attention. In this way, the issuance of a warning is associated with a situation of special risk or a significant threat in the public health arena that refers, in this case, to NPSs or emerging drug phenomena.

The objective of a warning is to stimulate the attention of those receiving the message, emphasizing the importance of a significant event or phenomenon that requires special vigilance, control or precaution. For example, it may be relevant to attract the attention of health services and specialized institutions and to focus on the occurrence of a particular phenomenon that may present serious health consequences or risks. The issuance of warnings, therefore, becomes an inescapable task and justification for the EWS.

Once information on an event is reported to the EWS and has been validated, coordination —jointly or not— by the remaining members

of the system might trigger a warning on the matter. During the decision-making process, the seriousness or importance of such an event in terms of its impact on the welfare of the population will be assessed. It is understood that a warning will reflect those events or issues that, by their very nature, have special relevance according to the criteria of the EWS. Other events may be reported to the system and remain monitored for some time, but they will never be subject to a warning.

The warning shall contain information on a special event and may be developed from data provided by one of the EWS's members or may be a more complex communication output that gathers information provided by different members on the same phenomenon, thus capturing different dimensions of the system. Whenever possible, it is suggested that the warning meets the characteristics of the latter. In any scenario, you have to keep in mind that the information will always be limited, and there will be unanswered questions; yet there are events that due to their importance or possible impact, need to be disclosed so that action can be taken.

A warning can be limited to specific members of the network or be directed to other external stakeholders of the EWS (representatives of health services or institutions, including the general public) depending on the seriousness of the situation and potential impact.



Warning

Summarized and structured information on a public health threat associated with NPSs or with the emerging drug phenomena, prepared and sent by the EWS to specific recipients to avoid negative impacts on public health. Surveillance status of a public health threat associated with NPS or drug phenomena.

Depending on the target audience, warnings shall be:

- a) Restricted to the EWS network, exclusively targeting members of the system.
- b) Restricted to professionals who do not necessarily belong to the EWS network. For example, institutions working on reducing drug consumption, institutions working on drug supply reduction, emergency settings/emergency rooms, toxicological emergency services, treatment services for drug use, relevant civil society organizations.
- c) Restricted to the general public: warnings directed at the general population or "Public Warnings". These may be directed to the entire population or to a specific segment (example: regional warnings issued to the population of a specific area of the country).

Review the institutions or stakeholders in the country that can be linked to the process of issuing alerts.

It is important to bear in mind that several steps must be taken between a report being developed and shared within the network on a given phenomenon, and its dissemination as a "Warning" that can be communicated to specific partners outside the network or even among mass media for dissemination to the general public.

In general terms, the procedure would be:

- If the EWS receives important information (for example, death related to an unusual substance), the coordinating entity must first share the information with other members in the system, requesting that they pay particular attention to the report and, if possible,

provide more detailed information in accordance with the competence of their institution. In this way, the coordinating entity will collect information on the subject and share updates with the EWS's members.

- If the coordinating entity considers that additional information or more information can be provided by other institutions or stakeholders external to the EWS network, contact will be made with them requesting their support and collaboration. This situation and its development will be discussed within the network of the EWS and the National Drug Observatory. Considering the nature of the event, if it is determined that it is useful to inform programmes, services or institutions that provide care to drug users - since it can contribute to preventing associated harm-, the information will be provided in the form of a warning according to the recommended structure (see below). In other words, the warning is directed at specific institutions and programmes at this stage, and not towards the general public. This is why it is important that the EWS coordination has an up-to-date and complete list of institutions focused on prevention, treatment, and harm reduction for the correct dissemination of the warning among stakeholders. Publication in the mass media, the internet, or social networks should be the last step to consider in the dissemination of a warning. However, it is important to emphasize that the information generated and validated by the EWS should also be disseminated to relevant stakeholders in the health arena at different levels so that their expertise can be enriched by the information to improve their health care practices.

It may also be necessary for the information to be provided to other specific population groups or even to the general population. In this way, **the aim is to show that the issuance of warnings becomes a fundamental task for the EWS**; it is important that the EWS re-

tains its technical independence necessary to make such decisions and that its objectives are not disrupted by other (for example, political) interests which could potentially deter the issuance of such warnings.

The above requirement introduces one more challenge: that EWSs can develop communication products (in this case, "warnings") in line with the intended recipients.

This involves the proper search and selection of forms, content, communication channels, etc. to ensure the greatest impact of what is intended to be transmitted.

It is necessary to define in advance the content of the communication, which may vary from simple and brief information to a document describing different aspects of substances/phenomena. It is advisable then to make different types of communiqués according to the medium and target population.

Logically, this whole process will involve the EWS's consideration and evaluation of multiple aspects, since issuing a warning is not an easy task as it requires a detailed analysis of the available information, quality, safety, accuracy, and thoroughness.

In terms of a communication plan, we must think about the "how" and the "what" (communication tools); it is necessary to predict that such information will bring as a consequence, doubts, and consultations, both from specialized areas and from the general population. Therefore, the availability of communication tools to provide answers to the concerns raised should also be planned.

It may be prudent to offer direct channels of communication to the EWS or among some members of the EWS who can provide answers, for example, from the clinical or toxicological perspective.



Verification List of Information that should be included in Warnings

What?: What is happening? What is the subject of the warning, what is the potential threat to public health?

Who?: Which group of drug users is subject to a warning? Which group is at risk?

When?: Date of the warning to be issued? When was the threat identified? How long did the threat last?

Where?: Spatial aspects: is it a matter at the national level or in some region or a specific city that is affected?

Why?: What is causing the problem and what is the threat to public health?

How?: Recommendations in relation to minimizing the risks and preventing harm at the individual level. Moreover, the alert must have instructions for the institutional representatives; how should they deal with the alert and the request for cooperation in terms of communicating whatever information is related to the subject of the alert.

When the warning is directed to members of the system, it should take the form of a structured document, generally sent via email by the EWS's coordination unit.

The warning must have the following information (assuming that it is available):

- Nature of the warning, providing a detailed description of the information available;
- Identification of the substance: name of the chemical substance including the name of the molecule, synonyms, abbreviations and street names;
- Chemical Group: classification of the chemical group to which the substance belongs (aminoindans, arylalkylamines, arylcyclohexylamines, benzodiazepines, synthetic cannabinoids, cathinones, indolalkylamines — F. E. tryptamines—, synthetic opioids, phenethylamines, derivatives of piperazine, piperidines, pyrrolidines, plants and extracts, other substances);
- Description of the effects on humans: described in the literature by drug users;
- Risk through abuse and potential for dependence: if it is available, information on the potential that the substance has for addiction;
- Date of formal notification: it should provide information on the first international notification and notification in the country;
- Information on seizures disrupted by supply control authorities;
- Information on reported cases of non-fatal poisoning related to the substances;
- References: if possible, links can be added to relevant sources of information such as scientific articles, meta-analysis, or press articles.

Besides, when a warning is issued to members in the EWS, we can request additional information they are aware of or any related details.

2.4.2. Public Warnings

The issuance of a warning must be carefully analysed and evaluated taking into account the severity of the threat and the likelihood of the situation becoming more severe. Mass media, internet or social media should be the last step to consider in disseminating a warning. When it is finally decided that a warning will be made public, information to the media should always be published by the EWS's coordination unit.



The decision by the recipients regarding any information will be determined by the phenomenon that is being monitored or reported, as well as its severity and general information. The latter will guide the type of communication which should be directed towards meeting the objectives of being a "warning" and not generating "alarm"; in this way, undesirable or counterproductive effects can be avoided. While the former involves active surveillance of a given event or phenomenon, the latter may involve situations of panic or media mismanagement that may be more harmful than what is intended.

This difference will also contribute to the defining elements of the recipient/s to which the item in question should be communicated.

When publishing any information of interest to the EWS, it is always necessary to carefully select the communication medium and to consider the unintended impact or consequences of such communication. The dissemination of warnings should be done in an ap-

appropriate manner to avoid further damage by causing curiosity among people who are non-consuming or contributing to the promotion of substances.

In this regard, it is important to recognize that communication on risk reduction using warnings on substances poses a communication challenge since a balance has to be struck between providing appropriate information to prevent harm while preventing the unintended consequences of the same communication. By the same token, the use of terms such as 'potent', 'strong', 'mortal', and 'toxic' to describe the substance may cause some individuals to search for or request it.

The following information should be provided when issuing this type of **public warning**:

- Nature of the warning.
- Description of the warning (what? who? when? how much? why?).
- Description of the risks given the context (what is the real threat?).
- Guidance on what to do and what not to do (practical things and advice).
- Date of the warning.
- Who issued the warning and contact details.

Apart from the above-mentioned, it is recommended that these warnings consider the following areas:

- They should be tailored to the specific needs of the target groups or groups at-risk (for example, injecting drug users, party-goers, clubbers, the LGBT community).
- They should have information and language that is simple, clear and consistent.

- They should summarize the information available to date.
- They can be geographically specific (city, region, national level) to ensure that warnings are directed only to those at-risk.
- They should incorporate messages aimed at understanding the risks, threats and adverse consequences.
- They should have recommendations to detect, diagnose the problem, minimize the risks and deal with adverse consequences.
- They should have instructions to facilitate communication and contact with the EWS unit.
- They should have links and references to obtain more information on the subject.
- They should use channels and credible institutions (for example, respected organizations) to disseminate said information.
- They should use appropriate means of communication for dissemination according to the nature of the threat to public health.

No details on the psychoactive effects of drugs should be communicated to the public to avoid raising the likelihood of experimentation.

Before warnings are made public the quality of the information validated through verifiable sources. Warnings can save lives; therefore, the "opportunity" may be an essential criterion to consider when weighing the balance between the quality of information and the need to warn the population quickly. The ideal situation is the balance to be achieved in each specific situation.

Once a warning is disseminated, it is important to get feedback on how target groups access and interpret the warning messages and whether they were effective.

2.5. Fifth Step. Implementing the Early Warning System

The first aspect of implementation is to validate and reach consensus among the EWS's members on the operating delivery and exchange system developed in the previous step. This implies that all members are aware of and accept how the system will operate and the modality for the exchange of data and information, which will take place in predetermined formats as presented in the next chapter.

One or more meetings should be held between the EWS's coordination unit and members where the system is formalized to become operational. In other words, EWS member institutions and stakeholders begin their vigilance and actively monitor the phenomena being addressed.

In addition to validating the operational framework and data collection tools, these startup meetings should record the relevant events or phenomena for which each member is expected to report.

A basic list (each country can incorporate others according to its context) of events that the EWS must report, is as follows:

- Identification of NPSs (obtained from seizures and/or other sources) and biological samples.
- Death associated (as a direct cause or as a concomitant fact) with a NPS or other drugs.
- Cases of non-fatal intoxication by NPS or other drugs that require medical assistance or hospitalization.
- Adverse effects associated with the use of NPSs or known drugs.
- Production of NPSs in a country.

- Cases in which NPSs are identified as diluents (a cutting agent used to increase the volume of another main drug).
- Cases in which NPSs are identified as adulterants of another major drug.
- Cases with an unusually high concentration of the active substance in drugs already known and/or commonly used.
- Cases with the presence of dangerous adulterants in drugs already known and/or commonly used.
- New patterns of drug use already known and/or commonly used that increase health risks.

It is important to emphasize here the relevance of **rapid** reporting of an occurrence of events previously mentioned so that the EWS functions optimally.

The concept of “rapid” assumes that the reporting of events to the EWS should be done promptly and in short, a time as possible, even if the information is incomplete. The system must collect information from current events in real time about the identified phenomenon or event.

If the time between notification of the event to the EWS and its discovery as a threat or danger is less, the efficiency of the network will be higher when issuing a warning. Impactful measures can, therefore, be implemented to reduce harm to public health.

It is suggested that a periodic reporting schedule be established for each stakeholder to confirm the non-occurrence of monitored phenomena. This, therefore, becomes an obligation for EWS members to communicate monthly, for example, that “There is no new event to report”. This mechanism will operate as a reminder for surveillance and for ongoing communication to the EWS.



Communication Support for the EWS

When talking about a Network and the exchange of information and communication between different stakeholders, the question that inevitably arises is, what is the best medium for this communication?

There are various options. In many cases, computer systems of varying capacity and power have been established to support the system's activities. These usually work by restricted access to registered users (with username and password) as a way to protect information collected by the EWS to make it available only to its members. These computer supports or platforms, which can assume different characteristics and technological capacity, have as one of its greatest advantages, the ability to provide a virtual space that is specially designed for the system's operations.

Communication between members is channelled on platforms using specific functions such as those related to the preparation/submission of reports/complaints/warnings, database information, geo-referencing information, availability of a library, access to systematized information on known NSPs and their characteristics (chemical, pharmacological, toxicological, consumption patterns), among others.

In addition to these functions, platforms can have forums, quick access to other sites of related interest, transmission of information or quick accessibility mechanisms on special information, among others. The system must offer all guarantees in terms of computer security and in terms of information that requires confidential or secure handling.

These computer tools help to **support and reaffirm the identity of the system** among members, promoting a sense of belonging that positively impacts its functioning.

The functioning of the EWS is not restricted to these supports, however. There are alternatives such as the exchange of information among members through private mailing lists.

Face to face meetings between participants is another resource used by the Early Warning System, some with computer platforms, and some without. While face to face exchange is always enriching, aiming to coordinate consistent meetings or meetings with regularity, can be very complex. While these exchanges are encouraged, it seems appropriate that they be one of the options available for the functioning of the system. These may be established with some pre-determined regularity or convened in case of special events/issues when deemed relevant by the EWS's coordination unit. Naturally, more than one communication modality can exist within the same EWS and it will be necessary to establish which type of communication will be chosen for each of the instances (reports, exchange in forums, transmission of documents for circulation, etc.).

2.6. Pilot Exercise to Validate the Operation of the Early Warning System

A simulation exercise of a particular case is a good way to conduct a pilot test of the EWS's performance. To this end, it is suggested that a meeting or workshop be held with EWS members during which a case is presented, and each of the steps established in the operation is examined and revised through roleplay. At the end of the simulation exercise, it is useful to reflect on what has been done, to discuss results, give opinions and suggestions of adjustments to be made.

A Case Study⁶

In country “x”, at a drug treatment centre, information was received from a young man who believes that in exchange for heroin, he was sold “Krokodil⁷” because injection of the drug caused severe irritation to the skin on his arm; he also experienced different symptoms from those previously felt with the heroin.

Detection Phase: since NPSs are presumed to exist on the market in that country, the treatment centre reports this information (event) to the EWS’s coordination unit (National Drug Observatory).

It should be noted that the case report must have an established protocol that allows for the collection of information that is vital to the process.

Characterization and Event Confirmation Phase: on receipt of the report, the EWS’s coordination should immediately confirm whether this drug (“Krokodil”) exists in the country. The main source of verification, in this case, is the lab examination of fluids from the young man, or obtaining the drug from the street (in the same place or area where the purchase was made by the young person) and then analyzing it in a lab.

Actually, the toxicology lab at the treatment centre analysed a sample of the young man’s blood and found metabolites that confirm that “Krokodil” was consumed. The report of the lab analysis should ideally form part of the documentation in this case; failing that, information on the analytical method and results of the analysis conducted should be provided to the EWS’s coordination unit.

6. Both phases and the proposed steps form a basic model to which adjustments can be made for each particular context.

7. Desomorphine, an opioid.

In this case, since the discovery of a new drug was confirmed, the search for information on it to determine the characterization of the substance is initiated. It is important therefore, to consider information about the particular case, collecting information on: presentation of the sample, characteristics of the packaging, photography of the sample, place, and date of the finding. In addition, it is necessary to seek information on the substance, such as health effects, toxicity, pharmacology, clinical manifestations, risks and associated damage, countries where the substance has been reported, documented deaths, poisoning, emergency admissions or other adverse effects associated with the use of the substance in other countries. There are several sources of information from international agencies where bibliography related to psychoactive substances can be found, including the following:

Resources on the Global SMART Programme

<https://www.UNODC.org/LSS/Page/NPSResources>

European Monitoring Centre on Drugs and Drug Addiction (EMCDDA)

<http://www.emcdda.europa.eu/activities/action-on-new-drugs>

Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG)

<http://www.swgdrug.org/>

Information on the characterisation of the substance is part of the case documentation and its format may be defined in advance and standardised, containing variables and information to be recorded.

Risk Assessment Phase: This phase analyses the information collected at the characterisation stage of the substance found, and evaluates it in order to make a decision on the issuance of the warning. In the case of the example given, after assessing the risks of

the substance with respect to the likelihood of severe poisoning, it is then determined to issue the warning by reporting the presence of "Krokodil".

The Issuing Phase of Warnings: the warning is designed and issued by adapting its content and defining channels for different recipients. In the example cited, it is critical to warn drug users circulating (consuming or purchasing the substance) in the area where the identified substance is being marketed, in particular, heroin users, considering that the young man intended to buy heroin and was sold "Krokodil". The health sector and police authorities must be informed of the finding to prepare themselves to deal with emergencies related to this consumption and activate controls that enable a reduction in the availability of the substance.



Considerations for the Implementation Phase

Note that the identification of substances is a central aspect of the EWS, which constitutes scientific evidence to define the nature of the event (new substance, diluting substances, purity, etc.). True identification is performed in the laboratory based on full identification of the substance or from analysis of biological samples.

Note that the National Drug Observatory should have the coordinating role for the EWS. This involves the collection, centralizing, systematizing, and disseminating information. At the outset, it must be agreed by all institutions and stakeholders that the National Drug Observatory will be responsible for coordination. It should also be noted that although members are involved on an equal basis, coordination and management of the EWS falls under the leadership of the National Drug Observatory.

MANAGEMENT AND MAINTENANCE OF THE EARLY WARNING SYSTEM

3

Once the steps described above in the manual have been completed, it could be said that the EWS is ready to function.

It is important to bear in mind that institutional logistics and the multiplicity of tasks and commitments undertaken by different stakeholders can generate some withdrawal from the system — even when they have officially expressed an interest in participation in the EWS— they may no longer participate in it actively.

For this reason, the role of the National Drug Observatory as coordinator of the EWS will be central to support the system (exchange of information), and therefore it is necessary that the tasks of coordination and management are consistent with the leadership, without which there is a risk of the EWS failing.

Some of the tasks carried out by management are of utmost importance to the function of the EWS.

3.1. Priority Tasks for the Early Warning System's Coordination

Monitor and maintain proper network formation which involves evaluating the incorporation of new members and taking the necessary steps in this regard (see Chapter 2 on the form of contact with the institutions and their meetings).

In the case of EWSs with a computer platform and access to previously registered users, the coordination unit should maintain access to new participants and provide any necessary advice for management of the platform.

Stimulate the active participation of EWS members whose main role is to transmit relevant information according to the objectives designed by the EWS. Members should also be involved as contributors towards the expansion of information on events reported by other members and in other activities programmed by the EWS's coordination. To this end, it is essential to keep all members involved and aware of issues, demonstrating the EWS's usefulness, benefits and involving them at different stages of EWS's final outputs.

Collect, centralize, systematize and analyse the information provided to the EWS by participants and the various outputs resulting from this process.

Validate the information received through triangulation of the information. Coordination of the EWS should aim to identify actual trends, events or occurrences that are relevant to the system. The triangulation of the information involves achieving sufficient completeness of data according to the objectives of the system and to the protocols already established in the EWS. This can be achieved by asking members and other relevant stakeholders for additional in-

formation than that initially provided, and aiming for (e.g.: consultants or international bodies, web portals, etc.) veracity or factual material.

Aim to keep the network active through the constant circulation of information and innovations in the system. This information will come from reports provided by the members, but also from the EWS's coordination; it will therefore be possible to include relevant content related to any topic such as research findings, scientific articles, new publications from international organizations, events of interest, etc.

Develop with members of the system (primarily seeking their endorsement and technical advice) **communication tools** to be issued to different recipients (for example, health centres, drug treatment centres, professionals, drug users, and the general public).

Disseminate warnings prepared by the Early Warning System to different relevant stakeholders (decision-makers, clinical settings, supply control agencies, health care and drug treatment centres, the general public, etc.).

Maintain sensitization of political bodies on the subject so that they can support the mandate of the EWS.

Monitoring other sources of information such as the media, social networks, discussion forums and specific Internet/Darknet sites (virtual stores and websites for the sale of NPS). It is important to monitor the drug market via the Internet to identify possible new substances that are being marketed¹. These undoubtedly constitute relevant sources of information on the emerging drug phenomenon,

1. For example, see the following guidelines: <http://cadap-eu.org/en/publications/surveys-and-monitoring/2017-guidelines-monitoring/>

as well as the media. Through numerous portals on the Internet, many specialised in the field of drugs, user forums and social networks, have access to a fairly wide range of information on drugs. These portals need to be monitored as they are created by the users themselves and, at the same time, are spaces where they consult to access substances, familiarize themselves with new items on the market, incorporating specific consumer practices (new or some that resurface after some time).

It is possible that in these spaces, practical guidelines for care are exchanged that are not always the most suitable. Web monitoring can provide very enriching information to the EWS, but unlike other sources, the task of coordination, monitoring communication channels to extract relevant information for sharing and exchange in the network, is key.

Promote research projects and activities that offer inputs to the phenomenon targeted by the EWS. These are *ad hoc* studies with EWS members that address some particular dimension of the subject.

3.2. Other Tasks in Coordinating the Early Warning System

With the Early Warning System operating on computer platforms, its updating and maintenance should fall under the supervision of the EWS's coordination unit to ensure that they are both tailored to the system's needs.

Invite members to participate in periodic meetings, either a segment of members or the entire membership where they can discuss specific subjects or new findings of interest to the EWS.

Develop and update different outputs from the EWS apart from warnings: databases, bulletins, global reports describing and analyzing trends of interest to the drug phenomenon, etc.

Promote and conduct **information exchanges** with other national and international EWSs.

Promote and organize meetings, symposia, seminars, conferences on the subject which all serve to provide a space for information exchange, updating the membership, including heightening the visibility of the EWS.

Stimulate and strengthen the capacity of members through **continuous education**. It is highly recommended that promotion and support be given to those bodies to encourage the development of different members in their respective areas on topics of interest for the EWS. Having analysed the current situation of the drug phenomenon in a specific country, as well as having contacted the different identified players, there will be difficulties to be faced.

On the other hand, the process of creating an EWS and its link to different institutions is a perfect opportunity to cater to training needs. The UNODC recognizes several challenges spurred by the proliferation of NPSs that have reached several sectors, such as health services, forensic labs for drugs, police, control agents, and legal queries. For example, forensic laboratories might be limited in their capacity to identify NPSs in drug samples or in biological samples. The authorities responsible for control may have difficulties in identifying new substances on the street. Legal authorities might not be familiar with the legal tools to be applied to control the production and trafficking of NPSs. Health services might not be prepared to identify or to act in response to NPSs use if they do not know their effects and their pharmacology.



Recommended Topics to Sensitize and Train Members of the EWS

- The problem of NPSs and the global emerging drug phenomena.
- Global Trends in NPSs.
- Production and Trafficking in NPSs.
- The Drug Market and Changes in Drug Policy.
- Legislative Responses for Control.
- Consumption and Effects of NPSs and the Emerging Drug Phenomena.
- Consumption of NPSs and its Impact on Public Health.
- Detection, Care and Reporting of NPSs and the Emerging Drug Phenomena on Health Services.
- Detection of NPSs in Labs.
- The Role of Adulterant.
- Detection of NPSs in Biological Sample.
- Monitoring and Surveillance of NPSs and the Emerging Drug Phenomena.
- Public Health Responses (prevention, risk reduction, harm reduction, and treatment of drug users).

Therefore, general and specific training are recommended periodically for stakeholders and other entities. It is necessary to bear in mind that one of the principal challenges is the detection of NPS.

This is a central aspect of the EWS because it is necessary to pay special attention to managing and strengthening forensic laboratories in a country on subjects such as detection skills, provision of reference standards, and equipment. Remember that through UNODC's Global SMART Program, there are technical resources for countries such as manuals on methods recommended to identify NPSs. Similarly, UNODC Vienna coordinates standards for quality assurance and supports the establishment of standards. Refer to <https://www.UNODC.org/LSS/Page/NPS/Resources>

3.3. Information Flow: Detection and Risk Assessment

The circulation of information within the EWS begins with the reporting of any event by any EWS member, including the National Drug Observatory itself, through instruments that will be presented below. This information can be transmitted in different formats according to its relevance or urgency.

Detection of a NPS or other Emerging Drug Phenomena. Starting with the most typical case, EWS members report the identification of a NPS or an event related to the emerging drug phenomenon: unusual adulterants, rare seizures or detections of controlled drugs, health problems linked to known drugs or the existence of dosage units (tablets, pills, etc.) containing an unusually higher concentration of an active substance (high potency drugs). For such cases, there is a report form to be used by EWS members in which the new identification is reported and sent to the coordination unit, even if the information is incomplete or unavailable at the time. After the EWS coordination unit receives the report form, all data is verified, especially if



Annex 5. Form for the Identification of NPS and Emerging Drug Phenomena

the reported substance or event has already been identified in the country in advance, or if it is the first identification. If the coordination unit receives an incomplete or missing report form, it must verify whether the missing data is inaccessible or simply report an omission when completing the form. It shall also verify whether the information provided is sufficient **to activate the action protocol** or whether additional data is required. At the stage of rapid collection and information exchange, it shall not be made available to the public and no additional information will be given on the identified substances; this allows for an evaluation to be performed and to consider other steps according to the nature of the findings. The verification of the reported data will be carried out preferably by email (or by phone and with email tracking), although it is also possible to use a website for this purpose with limited access only for system members. Finally, the report form will be completed and distributed to all members of the EWS network.

However, the logic in circulating information is not always the same among EWS models. There are EWSs whose methodology is described and assumes that in the coordination unit, information is centralized (reports), analysed (for example, its accuracy, its completeness, etc.), evaluated and validated and then shared with the rest of the network members. In other cases, the initial report of the members to the EWS can be automatically shared with the entire network without prior analysis by the coordination unit.

In either case, additional information may be promptly requested from the EWS's coordination unit when the information provided is considered insufficient. In these cases, an application may be made to the same member who issued the report and others according to the expertise of each member, and if necessary, to complement other approaches and/or disciplines. At this stage, other sources of information may be used, such as those external to EWS mem-

bers (international portals, research reports, etc.) to complete understanding about the event. When the information obtained is considered sufficient, a rapid risk analysis of the reported event may be performed. For this analysis, it is suggested that the National Drug Observatory remain in constant communication with the EWS members to make an accurate assessment of the event and to consider all the dimensions involved, and the key risks to health and social services.

Finally, if the assessment concludes that there is a risk to public health and that targeted communication can help to prevent or minimize the harm associated with drug use, the warning is launched and disseminated.

The goal is to avoid further damage related to exposure to NPSs or any other emerging drug phenomena. Depending on the seriousness of the threat, the warning will identify the target groups.

High risk or dangerous events identified by the EWS should be monitored. Adverse events such as fatal intoxication, non-fatal, but serious intoxication related to NPSs and other drugs merit monitoring. If the number of adverse health events increases, or new seizures are reported the EWS may propose disseminating an alert to specific stakeholders, such as services for drug users or treatment centers, or facilities specializing in emergency medicine. To maintain this level of coordination, EWS members are continuously requested to update the information (figure 4 and figure 5).

Some identifications and reported events can be categorized as “serious”. To determine the seriousness of a case, the following criteria may be considered (EMCDDA-Europol, 2007):

- Large quantity of material seized.
- Evidence of international trafficking.
- Evidence of group participation in organized crime.
- Pharmacological and toxicological properties of NPS or analogy with already known compounds.
- Evidence of the possibility of wider (rapid) dissemination.
- Evidence of intoxication that requires medical assistance or hospitalization.
- Evidence of deaths.

On the other hand, cases related to adverse health events should be declared on a specially designed form, and Annex 6 should be consulted.



Annex 6. Report Form on Adverse Health Events



To facilitate the identification of NPSs, Early Warning System information channels are used to circulate information on substances and their physical and chemical description. This often includes analytical data and spectra (for example, gas chromatography retention times, nuclear magnetic resonance spectra and mass).

To some extent, these data are substitutes for new psychoactive reference standards which are often not available. Information of this nature is exchanged by institutions that, as part of their activities, analyse drug samples or unknown substances (especially law enforcement agencies, toxicological and forensic laboratories).

Figure 4. Operational Functioning of the EWS

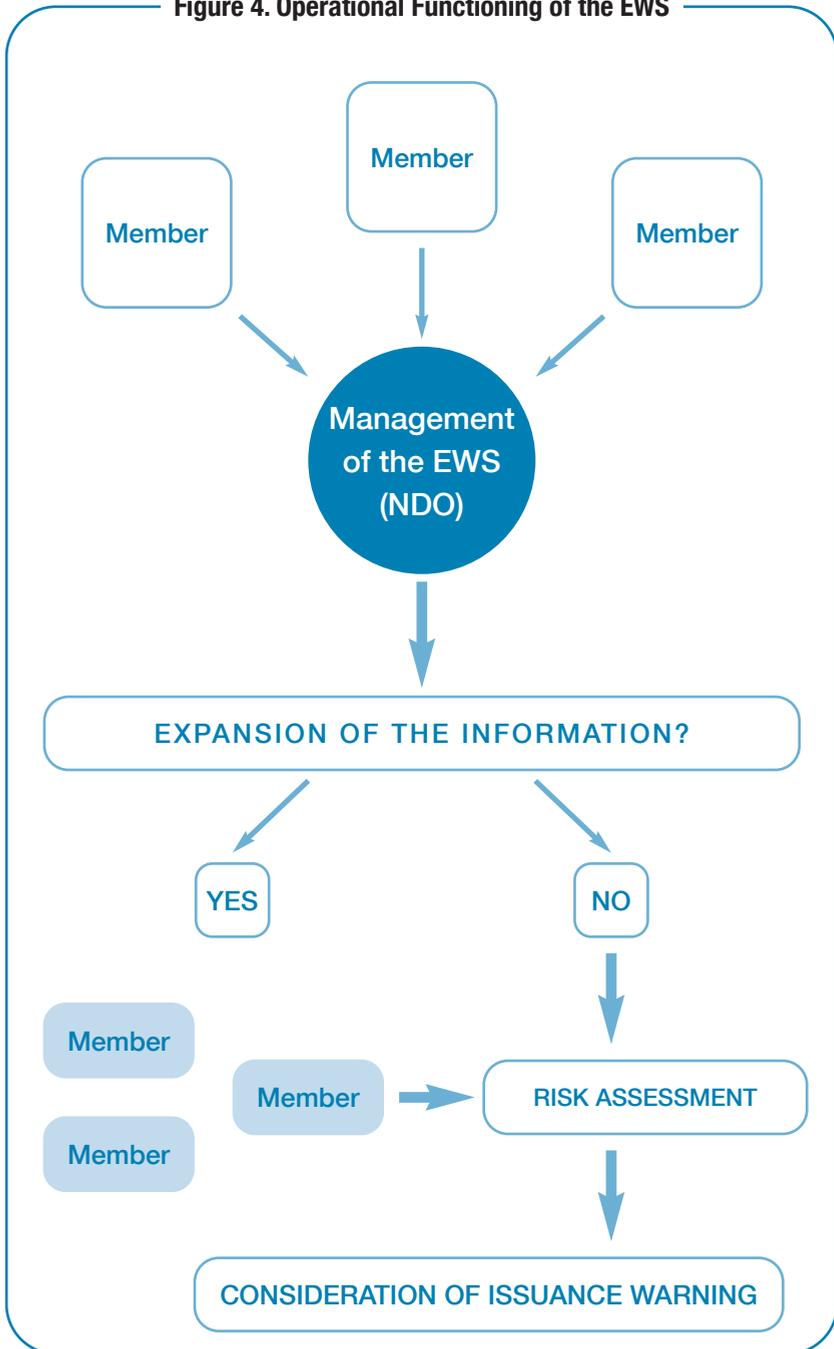
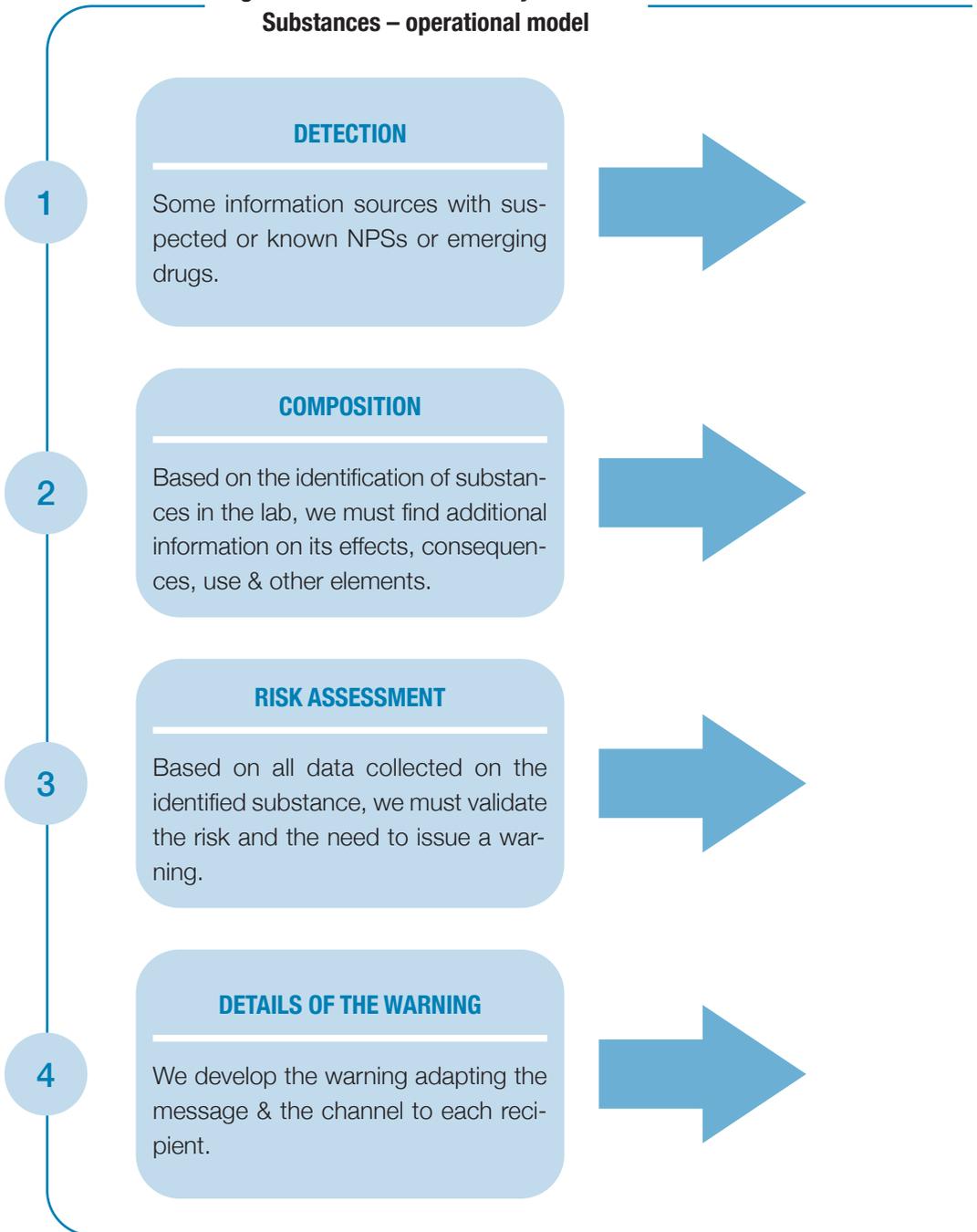
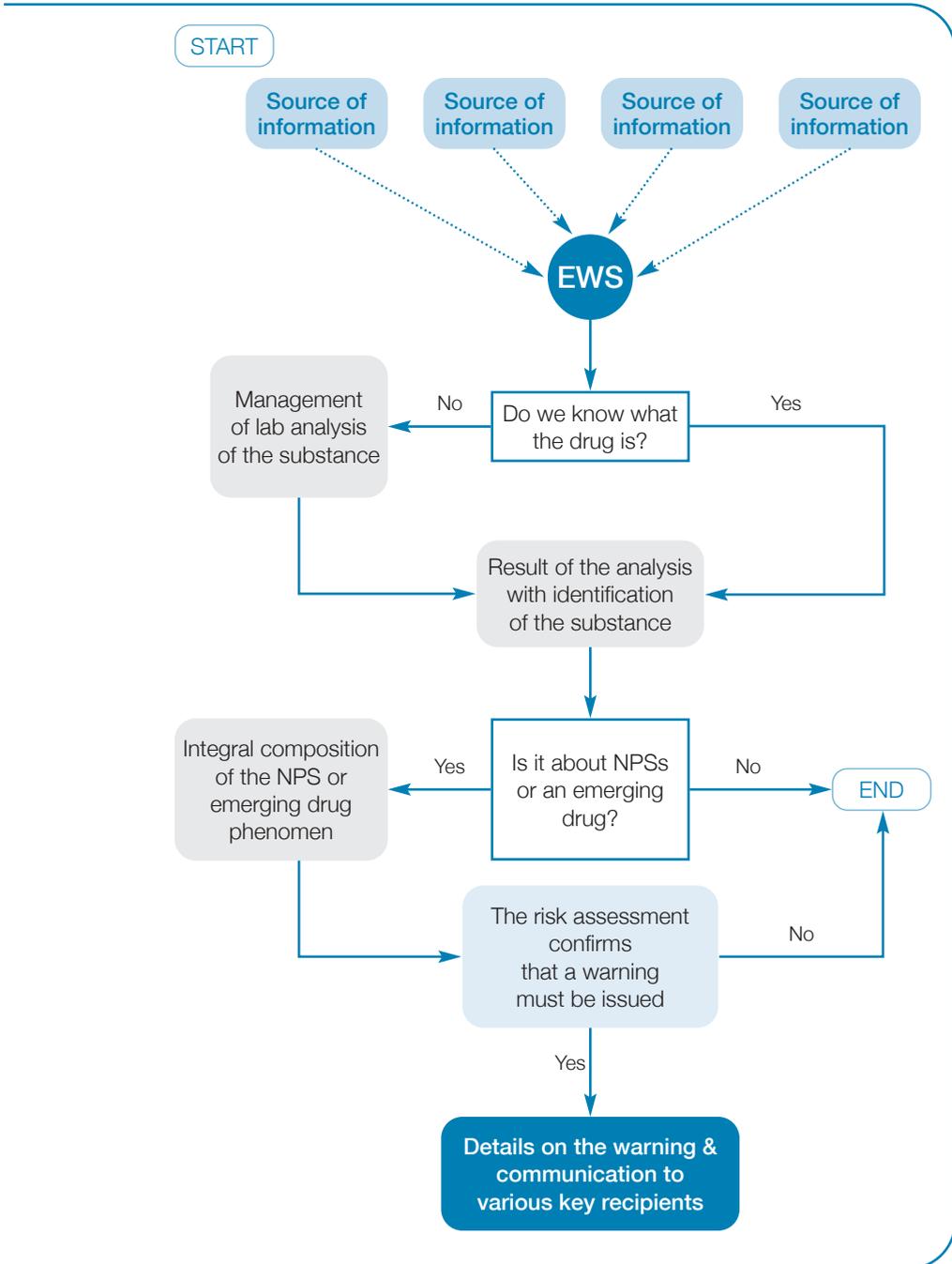


Figure 5. Detection of New Psychoactive Substances – operational model





Risk Assessment. In the case of a high probability of health threats from a reported event or phenomenon, the EWS's coordinating unit initiates the rapid collection of information through its members and other institutions or actors (according to the nature of the threat).

This phase involves assessing potential risks of its use to the health of drug users, the social costs, and the likelihood of expanding within or across populations. According to EU practice, the potential therapeutic or economic benefits of the use of an emerging drug, should also be considered.

The above information must be placed under the scrutiny of national and international scientific evidence available. Given that one of the limitations of the emerging drug phenomenon is limited availability and varying quality of information, better quality data should be prioritized, while still recognizing the value of data gathered with less scientific rigour (EMCDDA, 2009).

Ideally, data collection will focus on the following information:

- A chemical and physical description, including the name by which the NPS or other drug is known among users if applicable.
- Information on the frequency, circumstances and quantities of the drugs.
- Information on the means and manufacturing methods of the drugs.
- Information on the trafficking.
- Health and social risks associated.
- Prevalence of use among the population and specific sub-groups, user characteristics, patterns of use.
- Information on whether the drug is currently under assessment or has been assessed by the European Union or by the United Nations.

- Identification at the level of the European Union or at the international level.
- Information on whether the drug is subjected or not to control measures at the national level, by the European Union or internationally.
- Chemical precursors used in the manufacture of NPS or other drugs.
- Mode and extent of the established or expected use from the new substance.
- Any other usage of NPS or other drug and the extent of such use.
- Information on whether the NPS or other drug obtained commercial authorization or is the subject of an application for commercial authorization.

Risk assessment should be carried out quickly to strike the right balance between the collection of adequate information and rapid response. The latter means that risk assessment should not take too long, otherwise the possibility of taking rapid action on the event in question would be undermined. A warning may then be issued as a result of the risk assessment. Its content will depend on the issues to be communicated and the recipients of the message.

3.4. Instruments for the Collection and Exchange of Data

Standardized tools facilitate internal communication among EWS members, as they clearly set out the dimensions and variables to be communicated. EWS coordination also allows you to organize the relevant data that are collected and processed in each report. This mechanism undoubtedly optimizes the time and work of all parties, contributing to the efficiency of the system.

1) To collect and exchange data and information, it is recommended that adoption (or adaptation) of international reporting tools that facilitate the exchange of information, such as the ***Form for the Identification of NPS and Emerging Drug Phenomena***, adapted from the joint EMCDDA-Europol form.



Annex 5. Form for the Identification of NPS and Emerging Drug Phenomena

2) **Adverse health event reporting** form adapted from the form used by the EMCDDA.



Annex 6. Report Form on Adverse Health Events

The identification report on NPSs or emerging drug phenomenon, as well as the report on adverse health events may take the form of a questionnaire prepared in text editor or spreadsheet editor (for example, MS Office). The advantage of a spreadsheet file is the possibility of combining reports into a single file or loading reports into statistical software.



Consolidated EWSs can opt for more sophisticated data collection tools and mechanisms. They can distinguish between first identification of NPS (with a specially designed form) from subsequent occurrences of the same substance, which would not need to be immediately reported to the EWS. In these cases, the EWS could agree with members to report these cases, for example, every 3 or 6 months, using a tool specially designed for this purpose called "Periodic Report" where each detection is reported.

1) Report Form on the Identification of New Psychoactive Substances or Emerging Drug Phenomena

All EWS members who represent an important source of data on NPSs and emerging drug phenomena should use a report form on the identification of NPSs or emerging drug phenomena. This form should be used to report any information considered relevant to the objectives set by the EWS; for example, it may be of interest to record the occurrence of NPSs in biological samples even if they have already been identified in seizures, or cases of significant seizures of NPSs, among other scenarios.

Notification on the identification of NPSs or other drugs includes the following information (in cases where the information is available) (EMCDDA-Europol, 2007) (Decision 2005/387/JAI of the Commission of the European Union):

- Authority/Agency/Reporting Institution.
- Date of detection.
- Name of the substance (chemical name, other names like abbreviated names, street names). This includes the identification of adulterants.
- Source of information.
 - Physical sample originating from a seizure which represents confiscation of one or more psychoactive substances at a specific time and in one single location in the context of handling unauthorized cases of narcotic and psychotropic substances by law enforcement.
 - Human biological sample. For example, body fluids (urine, blood), hair samples, etc. The sample may be related to death, non-fatal intoxication, or some other reason why the sample was tested, such as driving under the influence of a drug.

- Physical sample from a sample collected as part of the active collection of drug monitoring systems or for research purposes (for example, controlled purchases from online stores or samples collected from drug users for verification of their contents).
- Other substances present.
- Physical description of the substance in the case of seizures/samples collected (powder, tablets, liquid, blotting paper) and characteristics, if applicable, of the dosage (weight, diameter, shape, logo/brand, other outstanding features).
- Extent of the drug market (production, trafficking, distribution or use).
- Price (retailer or wholesaler).
- Purity.
- Patterns of use.
- Effects on the person (according to sources of clinical analysis or from reports from the person).
- Context of use (specific user groups, consumer space).
- Indication of possible risks (social & health risks).
- Participation in organized crime groups.

Seizures of traditional drugs in unusually high concentrations, seizures of unusual or dangerous adulterants should also be reported to the EWS. In these cases, the following information is provided:

- Reporting authority, agency or institution.
- Date of seizure.
- Name of the substance.
- Information on the concentration or name of an adulterant.
- Information on the extent of the drug market.

- Origin of the substance (for example, purchase online through a distributor).
- Information on whether the substance was used by other people or whether other people are at risk.

2) Report Form on Adverse Health Events

Adverse health events are cases of serious intoxication that require medical assistance or hospitalization or fatal intoxications relative to:

- New Psychoactive Substances.
- Other drugs, for example, an unusually high concentration of traditional drugs, an unusual combination of drugs or unusual ingredients in traditional drugs.
- Adulterants and diluents.

Adverse health events are generally reported by toxicological labs or health centres, but they can also be reported by the police when they request it, for example, to investigate cases of death. Under these circumstances, the EWS coordination unit contacts relevant institutions and attempts to find out as much information as possible about the case. Personal identity data are not collected.

To get a complete picture, it is recommended that the tool to report adverse events relative to NPSs or substances already known include the following elements (adapted from the form for reporting adverse effects used by the EU-EWS):

- Name of the agency that provided the information.
- Date of the event.
- Type of event (fatal or non-fatal intoxication).

- Sex of the person.
- Age of the person.
- Type of biological sample(s) analysed (blood, urine, tissue, and organs).
- Specification of the method of analysis.
- Results of the analysis (values measured).
- Name and chemical name of the NPS or other drug identified.
- Information on exposure to any other analytically confirmed drugs, substances, or medicinal products from biological samples.
- Results from the analysis of other drugs, substances, medicines in the biological sample.
- Administration routes (oral, inhaled, injected).
- Physical form of the substance (powder, pills, capsules, solution).
- Source of the substance (internet, drug trafficker, friends, etc.).
- Description of the event.
- Description of the symptoms and clinical characteristics.
- Information on links to other cases of adverse events (other people who also take the substance/product at the same time and who require medical attention).
- Any other relevant information or comments.

The state of health and other consequences related to the use of NPSs or other drugs may also be reported by other stakeholders such as NGOs providing services to drug users or by the police. Since the information is based on subjective reports from drug users, the adverse event report form is not used for these purposes; this information is usually reported through more informal channels.

These two tools discussed above for data collection are used in the **detection phase**, the first phase identified in the functional diagram (figure 5). This enables the operation of the network to be activated, as noted above.

3.5 Dissemination of Information from Early Warning Systems

As noted above, information generation and communication are two of the key functions of the EWS. For this reason, one of the central pillars will be the capacity of the system to report in a timely manner. Achieving this ultimate goal represents one of the major challenges for EWS.

In this manner, information on events considered relevant should be transmitted to authorities and institutions concerned with supply control in order to strengthen controls and interdiction. It should also be transmitted to health sector institutions and stakeholders so that they can be prepared for potential demands for health services and social services. Finally, it is also useful to disseminate information to institutions or stakeholders involved in prevention, risk, and harm reduction.

To this end, the EWS will have to develop different products in line with each communication objective, depending on the recipient, the channel, and the message to be transmitted. Within this framework, the basic questions will be:

- What do you want to communicate?
 - How do you want to communicate?
 - Whom do you want to contact?



3.6. Outputs of the Early Warning System

There are various products that can be generated by the EWS, and these are the result of the analysis and validation of the information provided by different members.

Warnings

The main output of the EWS is warnings, and as already noted, the communication of risks associated with validated or confirmed phenomena is the *raison d'être* of the EWS. Chapter 2 of the Manual included the definition and main characteristics of warnings.

Communication on sensitive aspects, particularly where the focus is on public health, is not without difficulties. In this manner, myths are associated with the issuance of early warnings that can even limit the effectiveness of an EWS. Myths are founded on two types of fear: the information itself, and the public's response (see tables a and b).

Risk Assessment of Substances

The risk assessment phase already mentioned should include documentation of what has been achieved, the findings and conclusions reached regarding the phenomenon under study. These reports are products of this phase and are disseminated to members of the EWS network.

Database

The database is a structured system for storing information, for advanced processing, containing information reported to the EWS.

a) Myths referring to the Issuance of the Warning, its Source or Content

WHY THE MYTH LACK BASIS	ACTIONS TO COUNTERACT THE MYTHS
"The public's knowledge can worsen the situation"	
<p>Experience and research show that when there is a potential threat, it is better to pass on information so that something can be done about it.</p> <p>The consequences and costs are often very high when information is not provided. The challenge is to ensure that people are prepared to act with the information they receive.</p>	<p>Opening a constant flow of information as an incident develops, allows the initial guidelines to be modified as circumstances change.</p> <p>The public, knowing that the emergency unfolds, will modify its actions as the facts become evident and situations change.</p>
"The information should be as short as possible"	
<p>If the information is correct, it is unlikely to be too much when it comes to people's safety. Fear of the known is better than fear of the unknown. A balanced dose of accurate information can reduce speculation. Messages should be concise but complete.</p>	<p>Information should be provided as it becomes available.</p> <p>When events are uncertain, a warning is a dialogue that helps people deal constructively with uncertainty.</p>

Extracted from the International Federation of the Red Cross and Red Crescent Societies, 2012, page 17.

b) Myths referring to Responses to Warnings

WHY THE MYTH LACK BASIS	ACTIONS TO COUNTERACT THE MYTHS
“Crying wolf” (false alarm)	
The effectiveness of the public response to targeted warnings does not diminish when they are carefully explained and infrequent.	See false alarms as windows of opportunity: teach communities that false alarms arise from inherent uncertainty and not from poor professional practice.
Collective panic	
Collective panic occurs but is rare. Generally, people participate in adapted rational actions even when they are scared.	Timely and effective public warnings can do much to reduce the risk of panic in an emergency situation.

Extracted from the International Federation of the Red Cross and Red Crescent Societies, 2012, page 17.

The data is organized according to an accurately defined recording structure so that the information can be quickly found and used as needed. A database can be a useful tool for managing information on NPSs and other drugs identified at the national level.

The aim is to store information on individual substances, identify different sources, allowing information to be quickly extracted and analysed according to different criteria, thereby producing a summary of statistics. In addition, the systematization of this information facilitates international exchange, monitors detections on the local and international market, among other advantages.

A database on NPS and emerging drugs should include the following information:

- Date the substance was identified.
- Date of the report to the EWS.
- First identification (international, in the country).
- Case number (means confirmed occurrence, identification number of one or more NPSs at a given time and in one place).
- Place and circumstances of the detection (a seizure, intoxication or sample collection).
- Reporting authority (name of reporting authority, agency or company).
- Sample type (if the NPS was identified in a seizure, controlled purchase, collected sample, biological sample).
- Substance (name of the most widely detected NPS, including other names and street names).
- Chemical group (aminoidans, arilalquilamines, arylcyclohexylamines, benzodiazepines, synthetic cannabinoids, synthetic cathinones, indolalquilamines —for example, triptamines—, synthetic opioids, phenethylamines, piperazine derivatives, piperidine and pyrrolidines, plants and extracts, other substances).
- Other NPSs or substances detected in a sample.
- Physical form (tablets, capsules, blotting paper, liquid —blood, urine, other—, etc.).
- Quantity (weight or volume or number of tablets/capsules/blotting paper/etc. for the case).
- Unit of measurement.



Annex 5. Form for the Identification of NPS and Emerging Drug Phenomena

- Information on the market (production, trafficking/importation, trafficking/exportation, traffic-transit, distribution, use).
- Country of origin (or the last country before interception by another country).
- Destination country (for seizures).
- Molecular structure of the substance.
- Image/Photo of samples reported that contain substances.
- Risk Analysis associated with the use of the drug from the health and social standpoint (example: toxicological information).
- Information on chemical precursors.
- Method of consumption.
- Control measures affecting the drug.
- Notes (other data related to the case).

The database is managed from the EWS's coordination unit and should be made available electronically to other members of the network. In the case of the latter, access is permitted, but not data editing, the latter being the responsibility of EWS's coordination unit, which will incorporate developments into the database as new reports appear.

Protocols for Action

One of the products that EWSs can create is to generate specific protocols for action in clinical, forensic, and other areas.

When a NPS or an emerging drug is confirmed, changes or new procedures may be proposed that aim to deepen knowledge and to improve professional practice, for example, approaches by doctors or health specialists.

Bulletins/Reports with a Summary of Activities in the System for a Specific Period

Reports or newsletters that reflect cumulative reporting by members of the system or a collection of warnings issued by the EWS may also be another product generated by EWS. Other types of reports may also be prepared that collect specific information according to sub-topics of interest.

Proposals for *ad hoc* Studies

The EWS can provide an enabling environment to generate proposals for specific studies (and their development by some of its members according to their capacity and specificity) focused on responses to the emerging drug phenomenon. Such studies may involve other network members and provide insight into the subject matter being analysed.

Special Reports on Specific Themes using Different Methodologies

Promote and develop special reports to address particular topics related to NPSs or emerging drug phenomena arising from findings of EWS and participation by the system's membership. One of the methodologies applicable in this regard is Trendspotting (Mountney, 2016).

Documents for the Systematization of Legal Mechanisms and Procedures for the Analysis of Seized Substances

Information on various procedures should be summarized and organized for stakeholders involved; these will vary from country to country.

Summary Report

It is recommended that the EWS should periodically produce a document giving an overview of the situation concerning NPSs, emerging trends related to controlled substances, serious adverse events related to drugs and everything that was analysed in the EWS in a given period. The report should be viewed as a regular inventory of the situation. It is recommended that a summary report be prepared at least once a year (annual report) and that it covers five main areas, namely:

- The situation concerning NPSs (including the quantity of identified NPS), emerging trends related to controlled substances and serious adverse events related to psychoactive substances.
- Change in comparison with the previous year or, if possible, trends over the long term.
- NPSs that pose a substantial threat, usually those that have been subject to a past risk assessment, will require a specific section.
- Evaluation of the EWS network (for example, changes to the EWS network, formalization of procedures, activities).
- Legislative developments related to NPSs (for example, amendment of the list of controlled substances, adoption of new legislation).

To gain a better perspective, description of the situation can be supplemented by a table containing aggregated data on the identification of NPSs and other substances in different types of samples: seizures, biological samples or samples collected to map the drug market and emerging trends. It is recommended that the aggregated data table contain the following information:

- Institution, reporting authority.
- Type of detection (seizure, biological sample, collected sample).

- Name of the NPS or psychoactive substance detected.
- Other NPS or other detected psychoactive substance.
- Physical form in which NPS or other drug was detected.
- In the case of biological samples, information on the type of sample in which the new psychoactive or other drug was identified and whether the identification was related to a case of death, non-fatal intoxication or other cases, e.g., driving under the influence of drugs, drug testing.
- Total number of cases.
- Total quantity of seizures (total weight or volume, number of tablets/capsules/labels, etc.).

The report should be made available to all EWS members and should be sent to the national coordinating body on drug policy and public health authority responsible for the same. The report should also be made available to the public. However, it is recommended that an abridged version should be published which does not list all identified substances and which does not contain information on upcoming legislative changes.

The preparation of summary reports is the responsibility of the EWS's coordination unit; however, it may request members to make a summary report on the extent of their activities.

Reports to International Organizations

In the case of the first report on a NPS, particularly at the international level, it is recommended that the EWS's coordination unit report immediately to supranational organizations (UNODC, CICAD/OAS, EMCDDA), who will disseminate information on the identification of a NPS —including any analytical data— to institutions participating in the EWS at the global, European, and interna-

tional level (as national focal points, national units of Europol, the European Commission, the European Medicines Agency, etc.)

Information on substances identified at the European or international level is available for EWS coordination through access to the European Database on New Drugs (EDND)² and the Early Warning Platform on New Psychoactive Substances (EWA). The EDND is managed by EMCDDA and the EWA³ by UNODC.

Access to information on substances identified at the European and international level can be provided through an individual request to those institutions.

3.7. Recipients/Beneficiaries of the Early Warning System's Outputs

It is possible to identify seven types of direct recipients/beneficiaries of information and products produced by the EWS, in addition to the members of the system who, through information exchange, can increase their knowledge on a topic and improve their respective professional practice and duties.

a) Decision-makers

Within the framework of public policy, supported and evaluated based on evidence, it will be a priority to disseminate information and products produced by the EWS to authorities or stakeholders responsible for decision-making on drug demand and supply control reduction policies.

2. European Database on New Drugs (EDND) <https://ednd-cma.emcdda.europa.eu>

3. UNODC Early Warning Advisory (EWA) on New Psychoactive Substances (NPS) <https://www.unodc.org/LSS/Home/NPS>

b) Professionals/Experts from the Health Care Sector

This group, comprising professionals in the clinical field, either at the primary care level, emergency settings/services or in highly specialized health care settings, should have access to timely information developed by the system's framework because it is an essential component of their work. Informing these experts about the existence of certain substances, patterns of use, their effects, symptoms, toxicity, history of poisoning, overdose or death can help professionals improve the quality of their interventions by making more accurate diagnoses and by offering more appropriate treatments.

c) Interdiction Forces

Forces linked to interdiction tactics and supply control of psychoactive substances also constitute another group that can benefit from the information generated by the EWS framework, such as chemical characterization of unknown substances, knowledge of their morphological characteristics, the information provided by drug users or key source/source informants, forms of marketing and distribution.

d) Drug Users

Many drug users will be interested in knowing the chemical composition of substances they use, as well as the risks that such use entails, especially concerning synthetic drugs (and especially NPSs) because of their lack of knowledge about them. Information on the composition, dosage, and risks associated with use, as well as the appropriate dissemination of risk and harm reduction measures will allow users to incorporate care and behaviors that reduce consumer harm.

e) General Population

Information from the EWS can be useful not only for drug users but also for people around them (family members, friends or relatives) since it can provide information on care and actions they should take in case of acute intoxication. Mass dissemination of information with an emphasis on public health not only makes it possible to place the issue on the public agenda but also contributes to the de-stigmatization of drug users in society at large.

f) Other Countries

Bearing in mind that the phenomenon of NPSs, emerging drugs, and drugs, in general, is a problem that transcends borders and manifests itself globally, it is necessary that epidemiological surveillance has access to information from warnings issued by other countries and regions so that preventive measures can be taken in a timely manner.

g) Organizations and International Programmes (UNODC, CICAD/OAS, EMCDDA, COPOLAD, etc.)

International bodies monitor these phenomena throughout the world, collecting information, conducting specific analyses, and organizing forums for reflection and international action. Against this backdrop, it is essential that countries take the necessary measures to monitor this situation. Within this framework, it is also essential for them to have access to the information generated by national EWSs, to enrich and complement the regional and global analysis, which forms the main remit of these institutions.

Since 2014, the Commission on Narcotic Drugs Resolution 57/9, entitled *Improving international cooperation in recognizing and re-*

porting *New Psychoactive Substances and events relating to those substances*, stressed the need to detect, analyse and identify NPSs, aimed at both reducing demand and restricting supply to prevent abuse. It also urged "Member States to exchange, where appropriate, best practices on demand reduction measures, treatment guidelines and treatment practices based on scientific evidence, including information on the characteristics of consumption and the profile of consumers, always protecting their identity and privacy, in accordance with national legislation, in order to strengthen prevention strategies, rehabilitation, and treatment" (Commission on Narcotic Drugs, 2014).



In summary, this manual is intended to provide a practical guide with key considerations and fundamentals for the establishment of a national Early Warning System.

This manual is not intended to be a prescriptive guide to action protocols, information flows or tools for information exchange, but the concepts presented here must be taken as indicative and must be adapted to the reality and situation in each country.

Finally, because of their objective, Early Warning Systems are undoubtedly one of the essential pillars for preserving public health and safety of the population.

The provision of reliable information and evidence in real time, benefits all stakeholders involved and constitutes a unique value added to both supply control, demand reduction, drug policy formulation, and ultimately for drug users themselves.

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ANNEXES

ANNEX 1. ROAD MAP FOR PLANNING AN EARLY WARNING SYSTEM

JUSTIFICATION

Why is an Early Warning System necessary?

**What is the actual situation on New Psychoactive Substances
& the Emerging Drug Phenomena?**

DESCRIPTION OF THE PROBLEM

How is the information managed relative to New Psychoactive Substances & the Emerging Drug Phenomena?

.....

.....

.....

RESOURCES

Leadership Team: Who will be responsible for leading the process of establishing an Early Warning System?

.....

.....

.....

Financial Resources:

.....

.....

.....

Technological Resources:

.....

.....

.....

ANNEX 2. PLAN OF ACTION

WHAT?	HOW?		WHO?	WHEN?													
Objective	Activities	Indicator	Official Responsible	Year 1													
				1	2	3	4	5	6	7	8	9	10	11	12		
Identify the sources of information & the stakeholders	Develop a list of possible information sources & stakeholders																
	Send an informative letter to stakeholders identified																
	Organize a meeting with each institution																
	Convene a meeting with all stakeholders																

ANNEX 4. CATEGORIZATION FORM FOR FORENSIC LABS

GENERAL INFORMATION

Name of the Lab:

.....

Owner of the Lab:

.....

Address:

.....

City:

.....

Contact Number:

.....

Email:

.....

TYPE OF SAMPLES ANALYSED

Seizures:

.....

Biological Samples:

.....

Samples Collected from Drug Users:

.....

.....

AVAILABLE SERVICES

Select those available from the list below.

Colorimetric Reactions

Thin Layer Chromatography (TLC)

High Performance Liquid Chromatography (HPLC-UV-VIS)

High Performance Liquid Chromatography
with Diode Array Detector (HPLC-DAD)

Gas Chromatography with Nitrogen
Phosphorus Detector (GC-NPD)

Gas Chromatography
with Electron Capture Detector (GC-ECD)

Gas Chromatography
with Flame Ionization Detector (GC-FID)

Fourier Transformed Infrared Spectrophotometer (FTIR)

Nuclear Magnetic Resonance (NMR)

High Performance Liquid Chromatography
with Selective Mass Detector (HPLC-MS)

High Performance Liquid Chromatography
Mass Spectrometry (HPLC-MS)

Gas Chromatography with Mass Selective Detector (GC-MSD)

Ultraviolet Visible Spectrometer (UV/VIS)

RAMAN Spectrometer

High Performance Liquid Chromatography
with Selective Tandem Mass Detector (HRLC-SM/SM)

Microcrystal Tests

Others (specify)

NEW PSYCHOACTIVE SUBSTANCE QUALITY ASSURANCE AND DETECTION CAPACITY

Rules/Quality Assurance

National/International Certification/Accreditation

Use of Reference Patterns

List Available of Reference Patterns

Available Bookstores

List of New Psychoactive Substances detected in the Lab

List of New Psychoactive Substances that the Lab can detect

ANNEX 5. FORM FOR THE IDENTIFICATION OF NPS AND EMERGING DRUG PHENOMENA

REPORT FORM ON NEW PSYCHOACTIVE SUBSTANCES & EMERGING DRUG PHENOMENA*

1. Date:

2. Reporting Authority:

3. Chemical Name

Other Name(s):
.....

Street Names:
.....

4. Source of Information for the Sample

(indicate those that correspond)

Seizure(s)

Quantity Seized (weight, number of tablets, etc.):
.....

Person responsible for the Seizure:
.....

Date of the Seizure:
.....

Place of Seizure:
.....

* Adapted from the existing joint EMCDDA and Europol form (EMCDDA-Europol, 2007).

Biological Sample¹

Type of Sample:

- blood urine other

Sample related to:

- death(s) non-fatal intoxication

other (specify)

If you indicate "other", please specify why the sample was analysed (e.g.: driving a vehicle under the effects of drugs, drug treatment programme, etc.).

.....

.....

Concentration:

.....

Identifying Authority:

.....

Date of Identification:

.....

Place:

.....

Samples Collected²

Quantity (weight, number of tablets, etc.):

.....

Sample Collection Authority:

.....

Date:

.....

Place:

.....

1. Human biological sample, example, body fluids (urine, blood), tissue, hair, etc.
2. Actively collected by drug monitoring systems for monitoring or research purposes

5. Other Substances Present (if there is more than one case, identify which one):

Psychoactive Substance:

.....

Other Substances/Ingredients:

.....

6. Physical Description (in case of seizure/sample collected)

Type:

powder tablet capsule liquid stamp

other (specify)

Colour:

.....

For the Dosage Unit (e.g. tablets, cartons):

Weight:

.....

Diameter:

.....

Form:

.....

Logo/brand:

.....

Other distinguishing characteristics:

.....

.....

.....

7. Circumstances:

production trafficking distribution use

2. Recolectados activamente por los sistemas de monitoreo de drogas para fines de monitoreo o investigación.

8. Price:

Retail (by dosage unit):
.....

Wholesaler:
.....

9. Purity:

Part of an active substance

10. Pattern of Use:

.....

11. Effects on Humans:

Objectively observed:
.....

Subjective (descriptors by users):
.....

12. Context of Use:

Group(s) of users:
.....

Context:
.....

Availability for Consumption:
.....

13. Indication of Possible Risks (health & social):

.....

.....

14. Participation in Organized Crime

yes no unknown

ANNEX 6. REPORT FORM ON ADVERSE HEALTH EVENTS

NOTIFICATION FORM FOR ADVERSE HEALTH EVENTS*

1. Name of the agency providing the information:

.....

2. Date of the Event:

3. Type of Event:

Fatal Intoxication

Yes

No

4. Sex of the person:

Female

Male

Transgender

5. Age of the person:

* Adapted from the existing joint EMCDDA and Europol form (EMCDDA-Europol, 2007).

6. Biological sample(s) analysed

- blood urine tissue organs
 other (specify)

7. Specification of the methods of analysis:

.....

8. Results of the analysis (values measured):

.....

9. Name & chemical name of the identified NPS:

.....

10. Information on exposure to any other analytically confirmed drugs, substances, or medicinal products in the biological sample:

.....

11. Results of the analysis of other drugs, substances, or medicine in the biological sample:

.....

12. Administration routes for New Psychoactive Substances:

- oral inhalation injected smoked
 other (specify)

13. Physical form of New Psychoactive Substances:

- powder tablets pills capsule solution
 other (specify)

14. Source of New Psychoactive Substances:

- Internet drug trafficking friends
 other (specify)

15. Description of the Event:

.....

16. Description of the symptoms and clinical characteristics:

.....

17. Information on linkages with other cases of adverse events:

.....

18. Any other relevant information or comments:

.....

ANNEX 8. KEY INFORMATION ON NEW PSYCHOACTIVE SUBSTANCES AND THE EMERGING DRUG PHENOMENA

For some time now, the phenomenon of NPSs has been one of the most worrisome in the area of drugs. The emergence of this phenomenon dates back to 2008, while today, it presents as a expanding global phenomenon¹ characterized by its dynamism and its heterogeneity. It is a market where innovation is its strongest pillar.

The United Nations Office on Drugs and Crime (UNODC) defines NPSs as "substances of abuse, whether pure or prepared which are not controlled by the Single Convention on Narcotic Drugs, 1961, or by the Convention on Psychotropic Substances, 1971, and which may pose a threat to public health."²

NPSs are mainly synthetic products, but there are also substances of natural, animal, or vegetable origin. Many substances of natural origin are known, but few are widely abused or come to the attention of supply control agencies.

1. According to UNODC, it is necessary to take into account that in recent years there has been a substantial improvement in the instruments used to relieve and capture these types of phenomena, making them more specific and sensitive to NPS, so it should be taken into account this aspect when analyzing the increase of this type of substances in the international sphere.

2. It is necessary to point out that several substances currently receive the designation of NSP even when they have already been placed under international control, however, in the *2017 World Drug Report*, UNODC keeps them in this group for aspects related to the temporality of information and data availability.

The term "new" does not necessarily refer to new designer drugs —several NPSs were first synthesized 40 years ago— but are substances which have recently appeared on the market and which have not been incorporated into the aforementioned Conventions" (UNODC, 2014, page 2).

The definition of NPSs could also include industrial chemicals and related materials, as well as medicinal and veterinary products provided that they show psychoactive properties, and are being misused.

This very phenomenon has also been addressed under the name "Emerging Drug Phenomenon." According to the 6th Report of the Clinical Commission of the Spanish Government Delegation for the National Plan on Drugs, emerging drugs "are substances that appear on the drug market at a given time and are a novelty. They may be previously known or new drugs, they may have appeared before or never before, and are generally not listed as psychotropic or narcotic substances and are therefore not illegal." (DGPNSD, 2011, page 17) NPSs include totally synthetic substances or even those of natural origin. Again, they do not refer to strictly new substances, but rather to drug occurrences or resurgences in the market. In fact, in some cases, they are a rediscovery of something already known but which is re-engineered in a different format from the original or common usage (DGPNSD, 2011).

Under the caption of Emerging Drug Phenomena are also included so-called new patterns of use or new forms of consumption.

As stated in the handbook prepared by the OFDT (2003), the emerging drug phenomena refer to a change related to drugs that is observed for the first time.

"The fact that it is a first observation can be linked to the fact that it is a new phenomenon or a pre-existing phenomenon that has not been observed before, but is observed for the first time. An emerging drug phenomenon may, for example, deal with a new pattern in use, a new drug, a new population, a new awareness, etc." (OFDT, 2003, page 22).

Therefore, under the name Emerging Drug Phenomena, changes in the composition of a substance (for example, high concentrations of a psycho-

active ingredient) are also included, detection of new adulterants, drugs contaminated with pathogens, in addition to the aforementioned changes in patterns of use which may entail new routes of administration, new contexts of use, etc. and may cause greater risks among the drug using population.

NPSs or emerging drug phenomena represent a diverse group of substances that are produced clandestinely; they seek to emulate and surpass the effects of substances of natural origin, and produce new ones by a variation in their chemical structure. In this way, they circumvent regulatory controls to which traditional substances are subjected.

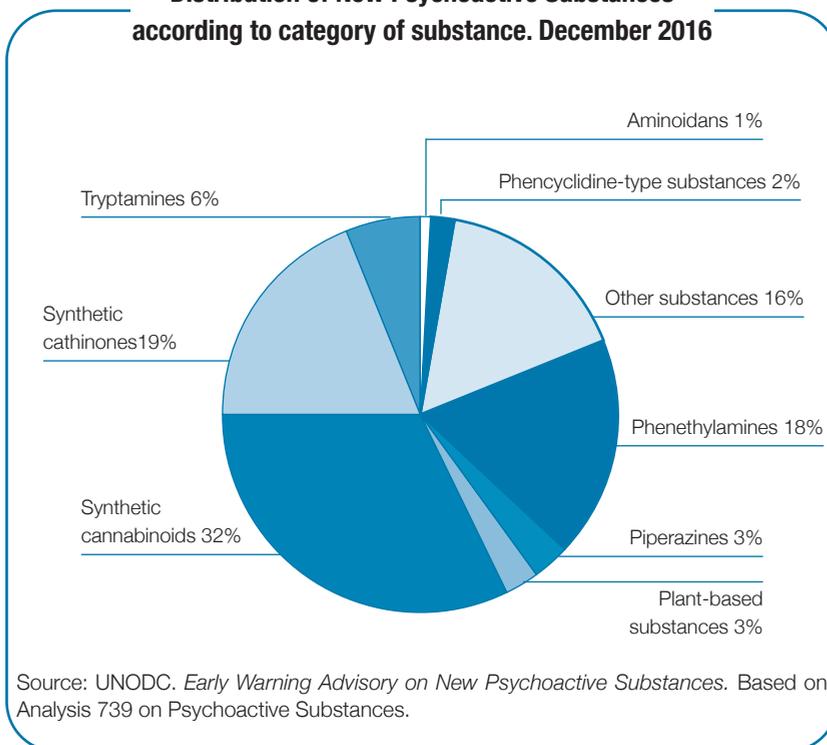
The *World Drug Report 2017* shows a trend already detected in previous analyses: the steady growth of the NPS market, which has never been as complex and as extensive as presently shown. NPSs are expanding at an unprecedented rate (UNODC, 2017, page 30). In fact, between 2009 and 2016, a total of 106 countries and territories reported the emergence of 739 different NPSs to UNODC (UNODC, 2017).

UNODC has identified 9 groups of NPSs according to their chemical structure, which in turn comprise various substances.

The groups are as follows:

- Aminoidans (for example: MDAI).
- Synthetic cannabinoids (for example: JWH-018, APINACA).
- Synthetic cathinones (for example: α -PVP).
- Phencyclidin type substances (ex: MXE).
- Phenethylamines (for example: MDMA, 2C-E, 25H-NBOMe).
- Piperazines (for example: BZP).
- Substances of vegetable origin (for example: salvia divinorum and khat).
- Tryptamines (for example: AMT).
- Other substances (for example: AMD). The latter group includes unknown drugs with little knowledge of their effects and/or their varied chemical structure.

Distribution of New Psychoactive Substances according to category of substance. December 2016

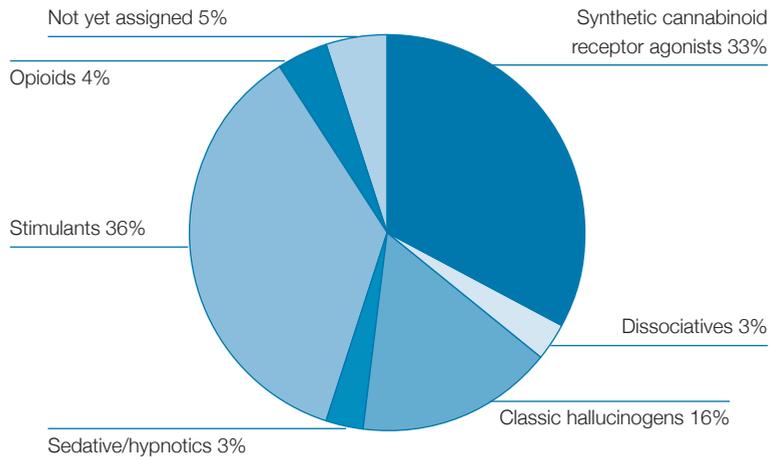


According to the latest data, synthetic cannabinoids constitute the largest NPS sub-group reported to UNODC, followed by cathinones and phenethylamines.

Another form of classification of NPSs is based on the pharmacological effects that they produce. This aspect is fundamental; it happens that substances with similar chemical structure produce different pharmacological effects, yet, on the contrary, a similar effect can be produced by a NPS of dissimilar chemical structure.

This classification shows the largest group of stimulants which comprise 36% of the total number of NPSs reported so far. The synthetic agonists of cannabinoid receptors then reach 33%, and the classic hallucinogens, 5%. The remaining groups meet less than 5% if analysed separately.

Distribution of New Psychoactive Substances according to Pharmacological Effects. December 2016.



Source: UNODC. *Early Warning Advisory on New Psychoactive Substances*. Based on Analysis 717 of New Psychoactive Substances (it does not include vegetable substances).

Finally, from a legislative perspective, new psychoactive substances are characterized as follows:

- Psychoactive substances are not currently included in any of the lists: a) the United Nations Single Convention on Narcotic Drugs, 1961, which may pose a threat to public health comparable to the substances listed in Schedule I or II or IV thereof, and b) the United Nations Convention on Psychotropic Substances, 1971, which may pose a threat to public health comparable to the substances listed in Schedule I or II or III or IV, thereof. This may include psychoactive substances currently not controlled or newly controlled psychoactive substances at the European level taking into account Council Decision 2005/387/JHA of 10 May, 2005 on information exchange, risk assessment and control of new psychoactive substances.

- Recently listed psychoactive substances are: a) the United Nations Single Convention on Narcotic Drugs, 1961 which may pose a threat to public health comparable to the substances listed in Schedule I or II or IV thereof, and (b) the United Nations Convention on Psychotropic Substances, 1971, which may pose a threat to public health comparable to the substances listed in Schedule I or II or III or IV thereof. In the case of newly controlled substances, these are placed under international control and the previous 10 years are considered.

CONSUMPTION AND THE MARKET FOR NEW PSYCHOACTIVE SUBSTANCES

Estimating the global use of NPSs remains a serious challenge despite the fact that in recent years more information on NPSs is available. One aspect linked to this is the lack of knowledge among drug users regarding the type of substance they consume; this creates concomitant limitations of data obtained through declarations of consumption in surveys. Another aspect that impacts the estimation of consumption is the variability associated with NPS categorization itself which may be different between different surveys and even within the definitions provided by UNODC itself (UNODC, 2017).

In addition, traditional research methods (surveys) used to estimate the presence of these substances also present limitations as in the case of studies on low magnitude phenomena that manifests itself in specific sub-populations and are thus invisible.

From the point of view of chemical characterization, the identification of these substances also presents serious problems either due to the lack of libraries or the difficulty in accessing those that already exist, especially in countries with limited resources.

Information from the supply control area also presents difficulties as the recording of seizures often falls outside national and international control systems. However, it is known that even with the large explosion of these

substances, the global market for these types of drugs is still small in terms of volume compared to other substances (UNODC, 2017).

All these constraints present profound challenges to risk management in public policy, posing a real challenge to those attempting to address the phenomenon and its health, social and economic consequences.

Despite this situation, it is well known that the market for NPSs is not intractable because there are differences between substances in terms of their "shelf life" in the drug market, some of which have maintained permanence, such as synthetic cannabinoids or amphetamine analogues, while others appear to have disappeared from the market. In any case, caution should be exercised with regard to the disappearance of certain substances given the existing problems with their chemical identification. (UNODC, 2017).

ANNEX 9. DESCRIPTION OF EARLY WARNING SYSTEMS IN THE INTERNATIONAL ARENA

The aim of this section is to provide information about the various international experiences in the field of Early Warning Systems and efforts made to address the Emerging Drug Phenomena.

UNODC'S GLOBAL PROGRAMME, SMART

The recent emergence and expansion of the global market for synthetic drugs and in particular the NPSs has caused concern among various international bodies such as the United Nations specialized office, UNODC (United Nations Office on Drugs and Crime) given the risks and damage that use of these substances have shown.

Therefore, there is a need to respond to the problem of use of these substances by implementing actions on monitoring, evaluation and information exchange among Member States (UNODC, 2014a).

Within this framework, the Global Monitoring Programme for Synthetic Drugs: Analysis, Reports & Trends (SMART), instituted in 2008, seeks to improve the capacity of Member States "through technical assistance to laboratory personnel, law enforcement and researchers to generate and use information on synthetic drugs, to develop effective programme policies and interventions" (UNODC, 2014a, page number not available).

The Global SMART Programme has three objectives in its programming:

- a) To build capacity for Member States to produce and manage information on the subject.
- b) To improve knowledge of the problem of synthetic drugs: making basic information and data available on the phenomenon.
- c) To support informed policy development: "Support Member States and international stakeholders on the use of information on synthetic drugs for drug policy development." (UNODC, 2014, page number not available).

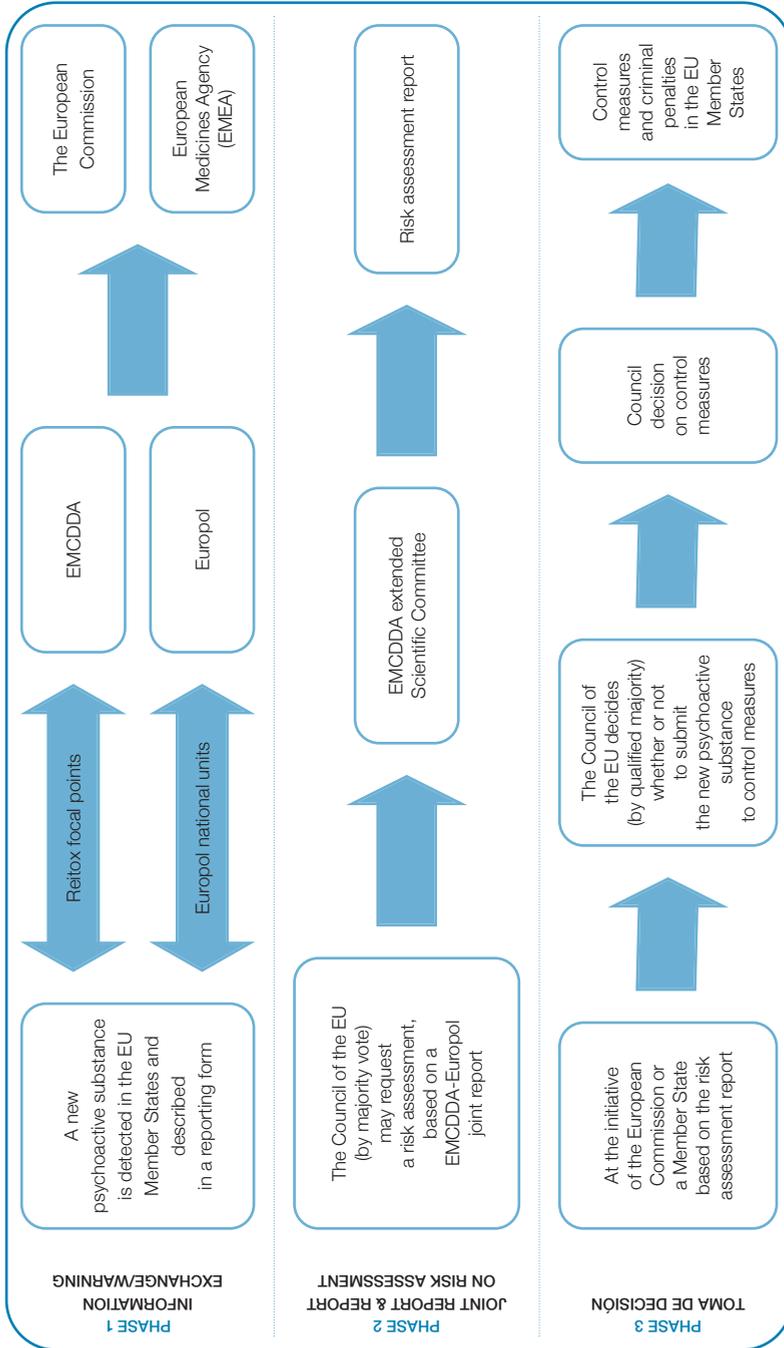
The first global assessment on synthetic drugs was conducted in 2013 based on information provided by countries and the Network of Laboratories participating in the International Collaborative Exercise programme (IQAP - ICE) by UNODC. Since then, it has sought to establish an electronic portal for ICE with the aim of transforming it into the global reference on NPSs.

The Programme leads the way in developing what has been called Early Warning Advisories (EWAs) on NPSs. UNODC's New Psychoactive Substance Early Warning Advisory helps to identify NPSs for international review, taking into account geographical prevalence and persistence.

THE EUROPEAN UNION'S EARLY WARNING SYSTEM (EU/EWS)

This is a unique regional system, a pioneer among Early Warning Systems on New Psychoactive Substances, with more than 20 years of experience, and one that responds at the European level to the phenomenon of new psychoactive substances and emerging drugs.

In 1997, by decision taken by the Council of the European Union (Joint Action 97/396/JHA), a three step approach was established: rapid information exchange, risk assessment and implementation of control measures on new synthetic drugs. Subsequently, under a new Council decision



Source: DGPNSD, 2017.

taken in 2005, this measure was also extended to substances of natural origin (EMCDDA-Europol, 2007).

The key stakeholders of the system are the Reitox Network with 30 focal points from each country (who in turn constitute National Early Warning Systems) which form an integrated multidisciplinary team with Customs, Toxicological Services, Chemical Services, Researchers, Europol and their National Units, EMCDDA, the European Medicine Agency (EMA), the European Commission and the European Council.

EU Member States must provide information on production, trafficking, use and preparations containing NPSs through reports already designed for this purpose. The information is sent through Europol's focal points and National Units to the EMCDDA and Europol, and then shared with all Member States, the European Commission and the European Medicines Agency (EMA) (EMCDDA-Europol, 2007).

On this basis, if Europol and the EMCDDA consider that the information requires monitoring, a Joint Report is prepared and submitted to the Council of the European Union, the European Commission and the EMA.

Afterwards, if deemed relevant, a Risk Assessment Report will be prepared by the Scientific Committee of the EMCDDA to include an assessment of social and health risks, use, production and trafficking of a given NPS, among other details.

If it wishes, it may be proposed that an NPS be placed under control; this will be determined by the Council of the European Union. If that happens, the Member States will have to adopt measures as soon as possible, but not more than a year. The measures to be taken will depend on legislation in each country (EMCDDA-Europol, 2007).

To this day, the system has a database that provides information on NPSs reported to the Early Warning System and also accesses focal points in each country. The system relies on 670 substances that are monitored.

NATIONAL EARLY WARNING SYSTEM (NEWS), UNITED STATES

The National Early Warning System (NEWS) has been operating in the United States since 2014 and was established through a cooperation agreement with the University of Maryland's Centre for Substance Abuse Research (CESAR) funded by the National Institute on Drug Abuse (NIDA).

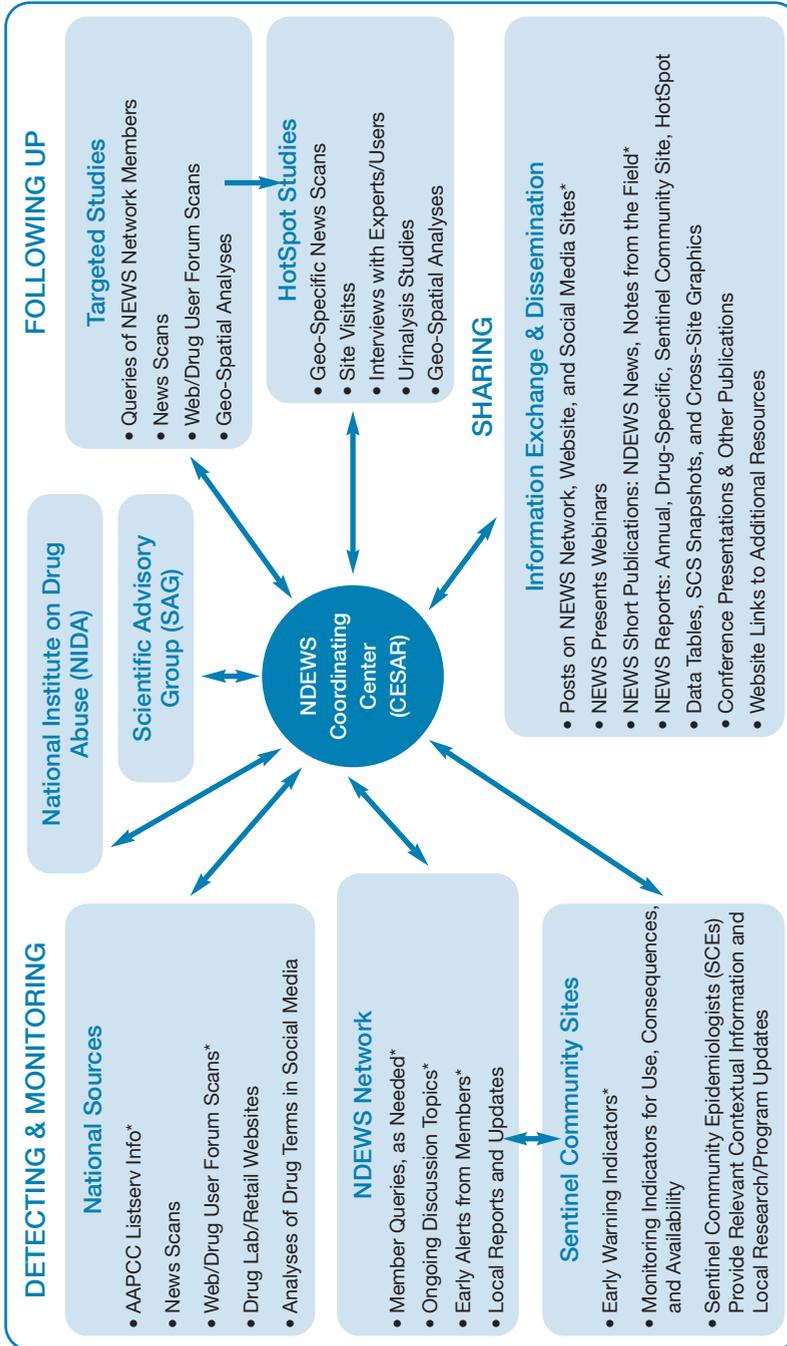
Based on the NIDA Community Epidemiology Working Group, the NEWS expands the network and incorporates national perspectives and new approaches to the emergence of new trends in drug use. It has sentinel sites that monitor drug trends, a virtual network of scientists, government institutions, public health experts, etc., who share information.

The National Early Warning System aims to detect, monitor and track these phenomena in order to achieve a better understanding (www.ndwes.umd.edu).

LATIN AMERICAN AND CARIBBEAN COUNTRIES (CELAC MEMBER STATES)

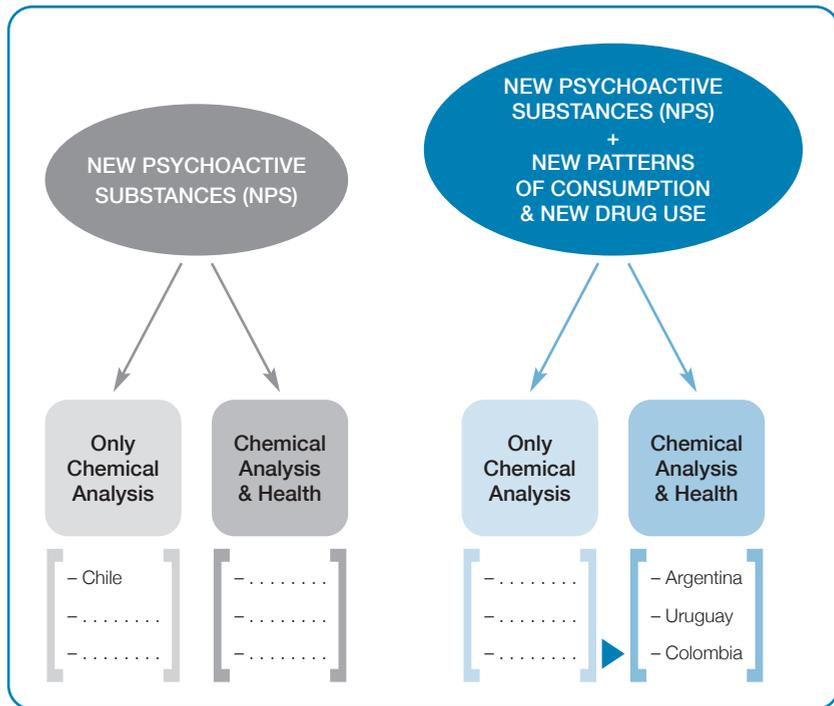
A survey carried out under the framework of COPOLAD II Programme, 2017 (led by Drug Observatories from Colombia and Uruguay on the characteristics and extent of Early Warning Systems in CELAC countries) indicated that countries with a functioning Early Warning System are Argentina, Chile, Colombia and Uruguay. There are similarities yet differences between them.

On one hand, Early Warning Systems in Argentina, Colombia and Uruguay have defined NPSs and new patterns of use and/or new uses of drugs already known to the surveillance. At the same time, these systems coincide in terms of the operational model used as cornerstones for chemical analysis of substances, analysis of clinical cases due to intoxication and/or overdose (health dimension) by NPSs as well as other substances or adulterants.



* Early Warning Component. Source: NEWS.

On the other hand, there is the case of Chile where the central objective is associated with NPSs, and the work is channeled solely through chemical analysis of these substances. The following outline shows the objectives and methods of their EWS (COPOLAD II, 2017).



Source: COPOLAD II, 2017.

In addition, Early Warning Systems in Argentina, Colombia and Uruguay are managed by their respective National Drug Observatory, while Chile's is administered through the Department of Controlled Chemicals (DSQC) by the Assistant Secretary to the Ministry of the Interior & Public Security (COPOLAD II, 2017).

In terms of structure, this highlights the heterogeneity at the level of institutional compliance with EWSs having more or less a wide and diverse

range of institutional participation, providing information for exchange. In all cases, there are all institutions in the area of Supply Control and Demand Reduction. In some cases, there is participation of entities external to these two areas (COPOLAD II, 2017).

As to the type of information handled, it should be noted that all Early Warning Systems agree on including data on seizures in their systems, chemical analysis of NPSs and other substances already known in the market and identification of adulterants present in drugs. However, they show diversity in terms of the outputs produced thus far, and the mechanisms to transmit and process information restricted to the Early Warning System network (COPOLAD II, 2017).

www.copolad.eu
info@copolad.eu
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SENAD Brazil

SENDA Chile

MINJUSTICIA Colombia

ICD Costa Rica

CND Cuba

VLADA Czech Republic

CND Dominican Republic

MREMH Ecuador

CNA El Salvador

GIZ Germany

DNII Honduras

CONADIC Mexico

CONAPRED Panama

DEVIDA Peru

NBDP Poland

SICAD Portugal

NAA Romania

DGPNSD Spain

NDC Trinidad and Tobago

JND Uruguay

ONA Venezuela

EUROPEAN UNION AGENCY

EMCDDA

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