

Central Asia Drug Action Programme, Phase 7

Technical Assistance Services for the improvement of data collection and analysis systems and the implementation of a Drug Early Warning System in Central Asian Countries

EARLY WARNING SYSTEMS ON NEW PSYCHOACTIVE SUBSTANCES IMPLEMENTATION MANUAL

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CADAP 7

Result 2

Technical Assistance Services for the improvement of data collection and analysis systems and the implementation of a Drug Early Warning System in Central Asian Countries

Deliverable 3

Early Warning Systems on New Psychoactive Substances Implementation Manual



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prepared by
Společnost Podané ruce
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1. Background

The Central Asia Drug Action Programme (CADAP) Programme in its Phase VII aims to support to Central Asian governments in the development of integrated and evidence-based drug policies and to improve access to quality drug demand reduction interventions to vulnerable groups incorporating a gender-conscious perspective and human rights-based approach (HRBA) in all interventions.

Společnost Podané ruce is stepping into this initiative by offering technical assistance, as outlined in contract APAS-2022-020, in order to achieve Result 2. The general objective of this result focuses on data collection, in particular on strengthening national information systems to gather and produce objective, reliable, gender sensitive and scientific standards-based information on the drug situation in Central Asia. In close cooperation with the governments of Kazakhstan, Turkmenistan, Tajikistan, Kyrgyzstan and Uzbekistan the technical assistance provided will bolster drug information and Early Warning Systems, especially concerning New Psychoactive Substances (NPS). This assistance aspires to amplify the efficacy of the data collection systems and methods in each of the CADAP participating countries. Enhanced data procedures will yield more dependable and thorough information, laying the foundation for evidence-informed drug strategies.

Moreover, the assistance prioritises the establishment of functional early warning systems in these nations, enabling the timely detection of nascent drug-related concerns. These systems empower authorities to address emerging challenges, curbing their detrimental effects. Designed for durability, efficiency and efficacy, these systems are crafted to serve long-term operational needs.

2. Overview

This manual has been developed under the framework of CADAP 7, specifically Result 2: *“Provide Technical Assistance Services for the improvement of data collection and analysis systems and the implementation of a Drug Early Warning System in Central Asian Countries”*, and within this Result, Deliverable 3, in the context of a collaborative effort among Central Asian countries, namely Uzbekistan, Turkmenistan, Kyrgyzstan, Tajikistan and Kazakhstan. This collaboration aims at strengthening the capacity for EWS in the region, focusing on the surveillance of New Psychoactive Substances (NPS) and emerging drug phenomena. The initiative forms part of a broader objective to enhance information exchange between the National Centre for Monitoring and Prevention of Drug Abuse, National Centres for Drug Control, Coordination Centre for Combating illicit trafficking of Narcotic Drugs, Psychotropic Substances and their Precursors, and other key ministries and institutions in these countries, thereby enabling a more effective response to new and evolving drug-related threats.

Given that the implementation of EWS is in its early stages in some Central Asian countries, this manual is designed to be a critical resource that complements and enhances the information already available within the different national monitoring institutions and coordination centres. At the same time, it introduces systems that are essential for responding promptly to the dynamic nature of drug-related issues. By doing so, it aims to significantly improve the response capacity and the effectiveness of interventions among professionals working in this field.

The coordination of EWSs, as proposed in this manual, falls within the remit of national drug coordinating and monitoring bodies, ministries and institutions of each country, considering the varied sizes, structures and approaches across Central Asian nations. Recognizing the unique political, legal, and administrative contexts of each country, the implementation of an EWS should be tailored to the specific needs of each nation.

An EWS, as defined here, is an inter-institutional, multidisciplinary network of key stakeholders that collaborates to detect early events posing public health threats due to the emergence of NPS or other drug phenomena. It also assesses risks associated with these substances and issues timely warnings to facilitate prompt and effective responses.

This manual draws upon established frameworks and experiences, including the EMCDDA's Building of a national drugs observatory: a joint handbook¹, the EMCDDA/Europol EU Early Warning System manuals and guidelines², and the COPOLAD's Early Warning System on NPS and Emerging Drug Phenomena: Implementation Manual³. It offers a generic EWS model that can be adapted to the unique situations and specific needs of Uzbekistan, Turkmenistan, Kyrgyzstan, Tajikistan, and Kazakhstan. The aim is to develop EWSs into reliable, effective, and efficient tools for stakeholders and contributors to drug policy development.

Comprising three chapters, along with bibliographical references and annexes, this manual covers the definition and objectives of an EWS, its operational aspects, and steps for effective implementation in Central Asian contexts. It also includes recommendations for EWS management, emphasizing the criticality of data collection, management, and the flow of information, and provides tools for internal communication and the issuance of warnings.

¹ https://www.emcdda.europa.eu/publications/joint/ndo-handbook_en

² https://www.emcdda.europa.eu/publications/guidelines/early-warning-system_en

https://www.emcdda.europa.eu/publications/guidelines/operating-guidelines-for-the-european-union-early-warning-system-on-new-psychoactive-substances_en

³ <https://copolad.eu/en/early-warning-system-on-nps-and-emerging-drug-phenomena-implementation-manual/>

3. Fundamental Elements of Early Warning Systems (EWSs)

3.1 Mission, general and specific objectives of EWSs

The mission of an Early Warning System (EWS) is to support public health and law enforcement. Its goal is to provide rapid responses to adverse changes in the drug landscape, aiming to minimize the risks associated with these changes.

The general objective of EWSs is to maintain a surveillance system incorporating information from multiple sources, including epidemiology, public health, and law enforcement. This system also tracks data on new psychoactive substances (NPS) and other emerging drug phenomena, supporting the development of swift interventions.

Specific objectives suggested for an EWS on drugs include:

- Providing rapid and accurate information on the NPS situation and other emerging drug phenomena in the market.
- Systematically monitoring the availability and consumption of NPS and other emerging drug phenomena, such as new consumption patterns, undisclosed or unusual events linked to drug use, significant quantities seized, and adverse effects related to drugs or their adulterants.
- Offering up-to-date information on the chemical composition (qualitative and quantitative analyses, including identification of main adulterants and diluents) of NPS and other 'traditional' substances already known in the market, particularly when a change in chemical composition that could pose health risks is suspected.
- Rapidly evaluating the risks and impacts associated with the use of NPS or emerging drug phenomena on user health, including pharmacological, clinical, and toxicological information.
- Quickly disseminating information on new NPS and emerging drug phenomena to professionals and, potentially, to the at-risk population.
- Depending on the EWS's mandate in each country, informing policymakers in the drug arena about NPS and emerging drug phenomena

Anticipated outcomes and contributions from the EWS

- Comprehensive understanding of NPS and emerging drug phenomena within the country.
- Reinforcement and enhancement of National Drug Information Systems in various countries.
- Significant contributions to the effectiveness of epidemiological surveillance by national drug policy coordination bodies (such as National Drug Councils).
- A more robust drug policy characterized by greater efficiency and rapid response, enabling relevant information gathering and timely interventions for drug demand reduction and supply control.
- Enhanced control of NPS through the implementation of effective legal measures.

Operationally, the Early Warning System functions as an institutional network comprising key stakeholders who are directly or indirectly involved in drug monitoring, drug policy, and drug control.

This network is ideally coordinated by a national drug observatory, driven by a specific purpose. The institutional network represents the collaboration and interaction among various institutions and key stakeholders. Each entity contributes, based on its functions and expertise, to the understanding and monitoring of the phenomenon, all guided by the specific purpose defining the EWS.

Forming this network enables the exchange of information and the development of joint actions and activities. An example is the assistance provided to control, inspection, and regulatory bodies through the provision of information on the identification of new psychoactive substances. This includes toxicological profiles and information about adulterants, which are sometimes more hazardous than the primary substance. Consequently, the identification of a new substance, be it an adulterant or a chemical precursor, can trigger control and regulation mechanisms. Utilizing various legislative and regulatory tools, which differ from country to country, the system aims to reduce the production and trafficking of these substances.

Analytical Aspects for the Early Warning System

For the Early Warning System (EWS) to effectively capture the key aspects of the phenomenon of new psychoactive substances and emerging drugs, it must encompass the following areas of analysis:

- Analysis of the chemical composition of substances, utilizing seized samples and/or samples collected from users or buyers on the Internet.
- Examination of clinical cases and biological samples linked to adverse effects, including deaths and intoxications, as well as results from autopsies and related investigations.
- Epidemiological monitoring of NPS use patterns and prevalence in a country in various settings (general population, nightlife, high-risk drug users) including quantitative (population) surveys, qualitative research.

3.2 Functional Structure

An Early Warning System (EWS) is a multidisciplinary, interagency network managed by key stakeholders addressing new drugs and new drug phenomena. This network is dedicated to generating and exchanging information with the goal of: (1) identifying early NPS, other emerging substances, and other drug-related events that pose a threat to public health, (2) evaluating the risks related to these phenomena and (3) responding to these phenomena by public health (awareness and warnings) and/or control measures.

Aligned with its mission and general objectives, the key functions of the EWS include:

- Facilitating information exchange among stakeholders within the system, ensuring a consistent flow of data on NPS and emerging drug phenomena from various sources and institutions once data collection methods are established.

- Creating a responsive and adaptable system poised to anticipate new events, fostering rapid information exchange and dissemination. This enables the development of timely responses and interventions for potential public health threats.
- Systemizing data collection and validating the compiled information on NPS and emerging drug phenomena.
- Issuing warnings to the network and relevant stakeholders, and making them public after evaluating potential unintended negative impacts. This is a crucial outcome of the EWS to mitigate risks associated with NPS and other drugs.
- Monitoring reported phenomena in the medium and long term to assess their progression and identify ongoing trends.
- Generating reports and other documents tailored for specific audiences, communicating various events and pertinent issues.

Additional suggested functions:

- Supporting international data collection mechanisms on NPS and drugs in general, led by agencies and programs like the United Nations Office on Drugs and Crime (UNODC), CARICC, EMCDDA, etc. This includes sharing national warnings and other relevant information, thereby contributing to the understanding of the phenomenon at national, regional, international, and global levels.
- Encouraging and backing research projects that offer insights and information relevant to the EWS, thereby strengthening scientific evidence.
- Organizing and promoting professional scientific meetings and exchanges on NPS and emerging drug phenomena to foster conceptual sharing and empirical knowledge, ensuring a unified comprehension of the situation.
- Advancing the training of expert members in their respective fields and activities, providing up-to-date and reliable information about events related to the emerging drug phenomenon at both national and international levels

3.3 Fundamental Concepts

- Establishing a multidisciplinary network of stakeholders and institutions that are key sources of information on the drug phenomenon. This network ensures the provision of diverse perspectives and information.
- Tailoring the system precisely to meet national and local needs in addressing the emerging drug phenomenon.
- Maintaining a proactive and responsive network to keep the system operational. A system with low activity risks becoming stagnant and ineffective. Therefore, one critical task is to ensure active involvement of EWS members to maintain steady participation levels.
- Prioritizing the exchange and usefulness of information among members and coordinating the EWS as a central aspect. The EWS should be recognized as a valuable tool for all participants.

- Respecting the mandate and competencies of the agencies participating in the network.
- Ensuring the relevance of information within the system to its set objectives. Circulating information that is irrelevant or inconsistent with the EWS's objectives can lead to confusion and dysfunction.
- Supporting scientific evidence, particularly focusing on chemical composition and harm assessment related to specific substances, and including insights from other disciplines such as epidemiology, social sciences, biology, preclinical studies, etc.
- Subjecting the information within the EWS to validation and quality control processes to ensure the development of reliable, evidence-based communication.
- Protecting and responsibly managing sensitive information within the system.
- Providing adequate human resources and infrastructure to ensure the optimal functioning of the system.
- Upholding good practices based on ethics, human rights, confidentiality, and professional transparency, both in the exchange of information and in its dissemination to network members and external parties.

3.4 Best Practices

- The presence of a **legal framework** that supports the establishment and operation of an EWS is crucial. Often, regulations can serve as a tool to ensure compliance with specific procedures, mechanisms, or actions. In the context of EWSs, it is observed that legal frameworks in various countries and regions facilitate the creation and operation of Early Warning Systems, covering aspects like operation, coverage, management, and institutional integration. These legal frameworks positively impact the systems by ensuring their functionality and longevity, as well as providing systematic coordination, sometimes with a degree of compulsion for certain levels or activities.
- **Standardized protocols and procedures** are essential. Protocols are guidelines that define the criteria or rules for activating certain actions, outputs, or processes. In EWSs, these protocols might cover areas such as the flow of information, treatment, validation, and dissemination of data within the system. Additionally, protocols might detail procedures for incorporating participants into the system (if not already defined in the regulatory frameworks). These tools aim to standardize and systematize responses or actions within the system, establishing clear coordination mechanisms for the system and its participants. The availability of protocols enhances the efficiency and proper functioning of the system. For instance, the joint handbook by EMCDDA and Europol (EMCDDA-Europol, 2007) offers guidelines for implementing the EU's EWS, detailing information flows and specific tools for exchanging information about NPSs in the European Union.
- **Specific resources** allocated for the Early Warning System are vital. Like in any field, the sustainability or continuity of projects or initiatives can be compromised if there are no dedicated resources for their operation. While the EWS can function without exclusive resources, its effectiveness and sustainability could be at risk without them.

- **Support** is necessary for material resources, including **financial and infrastructural**, to facilitate Early Warning System activities like communication and information exchange. Equally important is having professionals and technical staff who possess adequate time and training to carry out EWS tasks effectively.
- **System feedback** is crucial. Implementing various mechanisms for system feedback, along with systematic evaluation and enhancement over time, is essential for the continual improvement of the system (World Meteorological Organization, 2011).

3.5 Sensitive Characteristics of the Information Within the System

The information reported to the system should be inherently treated as sensitive, even though it is part of the internal management processes of the institutions and key stakeholders who contribute it. Additionally, some data may need to be corroborated or supplemented through triangulation with information from other sources. In light of this, the EWS must ensure the utmost confidentiality in handling this information. Consequently, access to the system should be secured with appropriate measures to instil confidence among its members. When circulating data and information, it should be clearly attributed to the contributing institutions and stakeholders. The methods of dissemination, along with guidelines for referencing or quoting the information, should be mutually agreed upon by these parties.

3.6 Administration and Institutional Affiliation

The EWS operates on different levels, encompassing systematic collection, organization, processing, analysis, and, where appropriate, rapid dissemination of information. For effective and efficient functionality, the EWS must be both inter-institutional and interdisciplinary.

Key institutions and stakeholders that form the network are the operational core of the EWS. They are tasked with providing relevant and timely information on specific events, aligning with the system's objectives. Key partners in the EWS include those involved in drug supply control, as substantial information is derived from drug seizures. Laboratories conducting chemical analyses of drugs (such as forensic institutes, universities, government agencies, etc.) are vital for identifying substances reported in the system. Health and treatment centres, particularly primary care, are also crucial due to their direct interaction with drug users, providing clinical and toxicological information, and contributing to the knowledge and best practices for the healthcare of drug users.

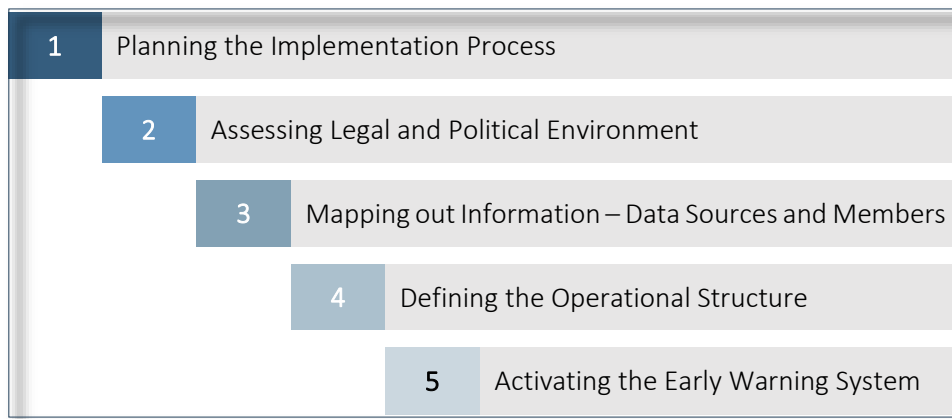
The EWS must undertake a coordinating role to ensure and encourage stakeholder participation, as well as be responsible for organizing, validating, and consolidating information, and for analysing this information, incorporating additional indicators wherever possible.

It is imperative for every country participating in CADAP to identify and designate a leading institution responsible for the development and coordination of the Early Warning System. This institution should be integrated into a comprehensive national drug monitoring and drug coordination mechanism that oversees and harmonizes the roles of various stakeholders, ensuring effective implementation of the national drug strategy. The integration of EWS within this framework is crucial to facilitate prompt detection and response to emerging drug threats, and to support a balanced and collaborative approach towards drug-related issues in the region.

4. Developing an Early Warning System

The present chapter is designed to offer guidance on operationalizing EWS. It outlines a structured framework for implementation, delineated through five specific steps detailed below. It is important to note that each country is expected to tailor its own model of the EWS, adapting it to fit its unique context and specific needs.

Figure 1 – Steps for implementing an EWS



4.1 Planning the Implementation Process

A critical prerequisite for starting the planning process is to establish the function, objectives, concepts, and other key elements of an EWS, as outlined in the preceding chapter.

Figure 2 – Planning the Implementation Process of an EWS



Understanding the context in which EWS is implemented is crucial. This involves being fully aware of the threats and trends related to New Psychoactive Substances (NPS) and emerging drug phenomena both regionally and internationally. Comprehending the process of identifying NPSs, the methods of information dissemination, and the stakeholders involved in these processes is vital.

Familiarizing oneself with the relevant institutions and stakeholders is central to the design of the EWS. It's essential to identify the experts who will lead the management of the EWS. Additional resources to consider include technology (an IT platform for managing the EWS's information) and finances (whether there are plans to hire staff specifically for the EWS or temporarily for meetings, events, and document production, etc.).

With the necessary human, technological, and financial resources, initiating the implementation of the EWS is not only possible but also highly feasible. This implementation can be further strengthened as the process progresses.

Recommended Activities

As part of the planning process for the implementation of the Early Warning System (EWS), prepare a document that includes the following components

Justification

Why is an Early Warning System necessary? Assess the current situation regarding New Psychoactive Substances (NPS) and emerging drug phenomena both nationally and internationally. What is the actual state of these issues?

Description of the Problem

Evaluate the current approach to managing NPS and emerging drug phenomena. Identify the challenges faced and discuss how an EWS could help address these issues.

Presentation of the EWS

Focus on outlining its goals, objectives, anticipated results, and expected outputs.

Objective

Define the purpose of the EWS. What outcomes are anticipated in terms of public health, drug control, and other relevant sectors?

Description

Detail the national reference point, describe pertinent information, and highlight the advantages of the EWS at the national level

4.2 Second Step: Assessing the Political and Legal Frameworks

In preparing for an Early Warning System it is crucial to examine multiple areas and engage in activities that promote its operation. This includes examining the political, legal, technical, and institutional frameworks, and considering institutional strengths and weaknesses.

Political Framework

The decision to implement an EWS should receive political approval from relevant authorities. This is often embodied in action protocols and working agreements between different institutions, departments, and/or ministries involved. If this is not achieved, it may be necessary to conduct sensitization and information sessions for political institutions and decision-makers on the threats posed by New Psychoactive Substances and emerging drug phenomena, as well as the role and impact of an EWS.

Legal Framework

International organizations provide guidelines emphasizing the need to monitor and track NPSs through an EWS. The United Nations Commission on Narcotic Drugs, for example, has adopted several resolutions related to NPSs and the need for monitoring systems, such as Resolution 48/1 (2005), Resolution 56/4 (2013), and Resolution 58/11 (2015). Furthermore, the operational recommendations from the 2016 Extraordinary Session of the United Nations General Assembly (UNGASS) document, titled 'Our joint commitment to effectively address and counter the global drug problem', include issues related to NPSs and the increasing challenges and threats they pose. Countries have committed to strengthening national and international efforts in this regard, highlighting the importance of EWSs in identifying NPS trends.

In the EU, EWS on new psychoactive substances is defined by the Regulation (EC) 1920/2006 (as amended by Regulation (EU) 2017/2101), and from 1 July 2024 will be replaced by the recently adopted Regulation (EU) 2023/1322. Control measures at EU level are defined in the Council Framework Decision 2004/757/JHA (as amended by the Directive (EU) 2017/2103)⁴.

In addition to international legal frameworks, the development and operation of a national EWS must align with a country's drug-related legal framework. As a preliminary step, compiling and analysing current regulations regarding drugs is essential. This legal framework can be the first output in setting up the EWS and will catalyse the involvement of partnering entities.

For instance, key EWS activities like managing drug sample data collection, chain of custody, lab receipt, chemical composition analysis, and communication of results must align with the competencies, authority, and functions of the involved institutions (mainly in health and supply reduction), considering lab analysis protocols established by each country.

When dealing with health or forensic sector information related to individuals, such as emergency drug cases or deaths, it's important to determine how this information will be registered in the EWS and any restrictions on public disclosure, respecting norms that protect personal data.

Each country has its own legal and procedural framework for analysing seized substances. It should be investigated whether substances not obtained from seizures can be analysed. For example, civil society organizations might have information or access to drugs from users that could be sent to forensic labs for analysis. Hence, for the EWS to function effectively, compiling information related to all these identified mechanisms and developing a document linking them is pertinent.

In summary, reviewing drug-related laws or norms, as well as the functions, competencies, procedures, and protocols of authorities and forensic labs, is essential. Often, drug legislation will define the boundaries of the EWS's operation.

4.3 Third Step: Mapping out Information – Data Sources and Members

The Early Warning System functions as a network for exchanging information, encompassing institutions and stakeholders involved in drug supply and demand reduction in each country, or those with related competencies and specific objectives. Identifying these entities is a crucial step for implementation.

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

Key stakeholders include forensic laboratories responsible for identifying or determining the chemical composition of seized substances in each country; they are pivotal in identifying New Psychoactive Substances (NPSs) and emerging drugs. Similarly, healthcare institutions with data on adverse health events related to drug use are vital for detecting NPSs or emerging drugs, particularly when they successfully identify the causative drug through biological sample analysis.

The EMCDDA recommends taking the following steps for creating an information map:

- Identify main counterparts, convey objectives to them, and organize an informational exchange meeting.
- Send an explanatory document to your contacts so they can arrange meetings with experts using potential information sources.
- Convene joint meetings with various experts and agency representatives to gather more information and foster connections.
- If in-person meetings are impractical (due to country size, budget constraints), consider video-conferencing or other virtual events attended by experts or institution managers.
- Post-meeting, send key discussion points to contacts, provide reference information, and analyse outcomes.
- Share the final version of the information map with stakeholders.
- Keep everyone informed about follow-up actions and results.

After mapping, the identified institutions should be engaged to become active parts of the EWS. This can be done through visits to each institution or by convening a meeting with all stakeholders, providing prior information about the intended objectives for preparedness.

One of the primary goals of the first meeting with stakeholders is to raise awareness about the threat of NPSs and the emerging drug phenomenon, emphasizing the importance of an EWS. The necessity of timely information exchange and the benefits of EWS membership should be highlighted. Each member must understand the advantages of participating in the system.

Additionally, it is necessary to define with each stakeholder their specific contribution to the EWS, including the information they will provide, its format, frequency, and any restrictions or special considerations required by the EWS.

Figure 3 - Priority Data for the EWS

1	Reports on Seizures of Psychoactive Substances
	Data including the date and place of seizure, type of drug seized, its presentation, quantity, method of concealment, origin/source, destination, route, and photos of the seized drug.
2	Chemical Characterization Profiling of NPSs and Other Psychoactive Substances
	Analyses conducted in laboratories equipped with appropriate technology and staffed by professionals trained to determine the composition of the substance, including concentrations where possible. This should cover the main psychoactive substance as well as any adulterants, diluents, solvents, and other substances
3	Identification of Patterns of Use/Administration of NPSs
	Information on consumption patterns of NPSs, including the setting for use, route of administration, frequency, intensity of use, combinations with other drugs
4	Identification of Other New Drug Phenomena New Drug Consumption Patterns
	Observations on "traditional" drugs or drugs already known in the local market, including different presentations, new routes of administration, new drug effects, and new contexts of consumption
5	Report of Clinical Cases of Intoxication/Overdoses of NPSs
	Expert reports from the health sector detailing the reason for consultation, the situation upon admission to the health centre, symptoms presented, substance consumed (based on analysis results or user's declaration), context of consumption, clinical and paraclinical studies and their results, diagnosis, medical indication (with or without pharmacology), progress, and discharge information. Data should include sex and age. This information should be anonymized and include known substances or adulterants
6	Toxicological Information from Autopsies
	Reporting the presence of psychoactive substances in a body, even if death was not directly caused by their use.
7	Report on the Harmful Health Effects of the Substances and/or Adulterants
	Information detailing the toxicological and clinical impact of the use of NPSs on people's health, whether from a substance already known in the local market or an adulterant.

A key aspect of the EWS's success lies in permanently strengthening institutional ties, facilitating information exchange, convening regular meetings, and maintaining active communication with all institutions in the network through various means.

In this regard, achieving two objectives is essential:

a. Identify and Engage with Institutional Representatives or Focal Points:

Meet with individuals who will act as the institutional representatives or focal points in the EWS. These focal points should represent their institutions and be expected to actively participate in the system.

b. Inform Institutions and Relevant Parties About Their Role in the EWS:

Clearly communicate to the institutions, and particularly to those concerned, the purpose of their participation in the system and the information required from their institution. It is necessary to establish the specifics of information provision and to train the institutional focal points on the operation of the system and their general responsibilities.

Guiding Questions

- What specific information is required, and which institutions or stakeholders have access to or can generate this information?
- Which entities possess the relevant expertise necessary for the detection of New Psychoactive Substances (NPS) and emerging drug phenomena?

When selecting institutions and key stakeholders to be part of the EWS, it is important to consider the following:

National Monitoring and National Information and Analytical Centres (National Drug Observatories)

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. Already established National Drug Observatories are natural candidates to play a leading role also in EWS.

Supply Control Forces: Ministry of the Interior, Ministry of Security, National/Local Police, National Customs and State Border Service, 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 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 Justice/General 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.

Forensic Expert Services/Crime/Toxicological/Clinical Laboratories

They conduct analyses of body fluids, biological samples (blood, urine, etc.), or 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. 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. 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.

Ministry of Health/Health Care Services/Republican Centres for Health Promotion (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 report their characteristics and evolution.

Specialized Health Care and Treatment for Drug Use/Drug Detoxification Centres/Clinical Centres for Addictions/Narcology 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 needles and syringe programmes, opioid substitution treatment (OST) centres, 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.

Youth Drop-in Centres, Counselling Centres, and Drug Prevention. Non-Government Organisations

Organisations 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.

Academic Research Teams Focused on the Drug Phenomena (Universities and Research Institutions)

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.

Global Early Warning Systems and Early Warning Systems from Other Countries; such as those in the European Union (EU EWS) and the UNODC (Global SMART Programme) are key sources for any EWS to stay informed about NPSs or emerging drugs at the regional and international levels.

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.

Framework with Priority data for an EWS and Potential Sources of Information

Report on Seizures

- Ministry of the Interior, Ministry of Security, National/Local Police
- State Border Service and National Customs
- Other Supervisory and Interdiction Authorities

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 of NPSs

- National Monitoring Centres
- National Information and Analytical Centres
- Health Care Services and
- Specialized Health Care and Treatment for Drug Use
- Low Threshold Risk and Harm Reduction Programmes
- Youth Drop-in Centres, Counselling Centres, and Drug Prevention
- Drug Users
- Detention Facilities
- Academic Research Teams

Identification of Other New Drug Phenomena

- National Monitoring Centres
- National Information and Analytical Centres
- Health Care Services specializing in Drugs
- Programmes/Demand Reduction interventions
- Youth Drop-in Centres, Counselling Centres Drug Users
- Detention Facilities
- Academic Research Teams

Reports of Clinical Cases of Intoxication/Overdose of NPSs, Substances already Known or Contaminants

- Health Care Services
- Specialized Health Care and Treatment for Drug Use
- Drug Detoxification Centres
- Clinical Centres for Addictions/Narcology Centres
- Academic Research Teams

Reports on Forensic Analysis of Death caused by Drug Consumption

- Forensic Expert Services/Crime/Toxicological/Clinical Laboratories

Toxicological Information on Autopsies(Indirect Mortality)

- Forensic Expert Services/Crime/Toxicological/Clinical Laboratories

All agencies or stakeholders listed above, as well as others not included here but potentially relevant, will benefit from their participation in the Early Warning System (EWS). By being part of the EWS, they will receive information that is of interest from the exchange generated within the system. The information circulated in the EWS can enhance the activities of each participant by providing inputs for the improvement of practices, the development of action protocols, anticipation of adverse or unwanted events, and a better understanding of the dimensions of the phenomenon, which may be less familiar to each of them.

Figure 3 presents a framework of priority data for the EWS, relating to the data these sources can provide for a global, dynamic vision of the EWS. It should be noted that this summary is not intended to exhaust all existing relationships between the data and its sources; rather, it highlights the most significant or common links. There are likely other data relevant to the EWS, as well as other pertinent sources, and different combinations between the two groups that may exist.

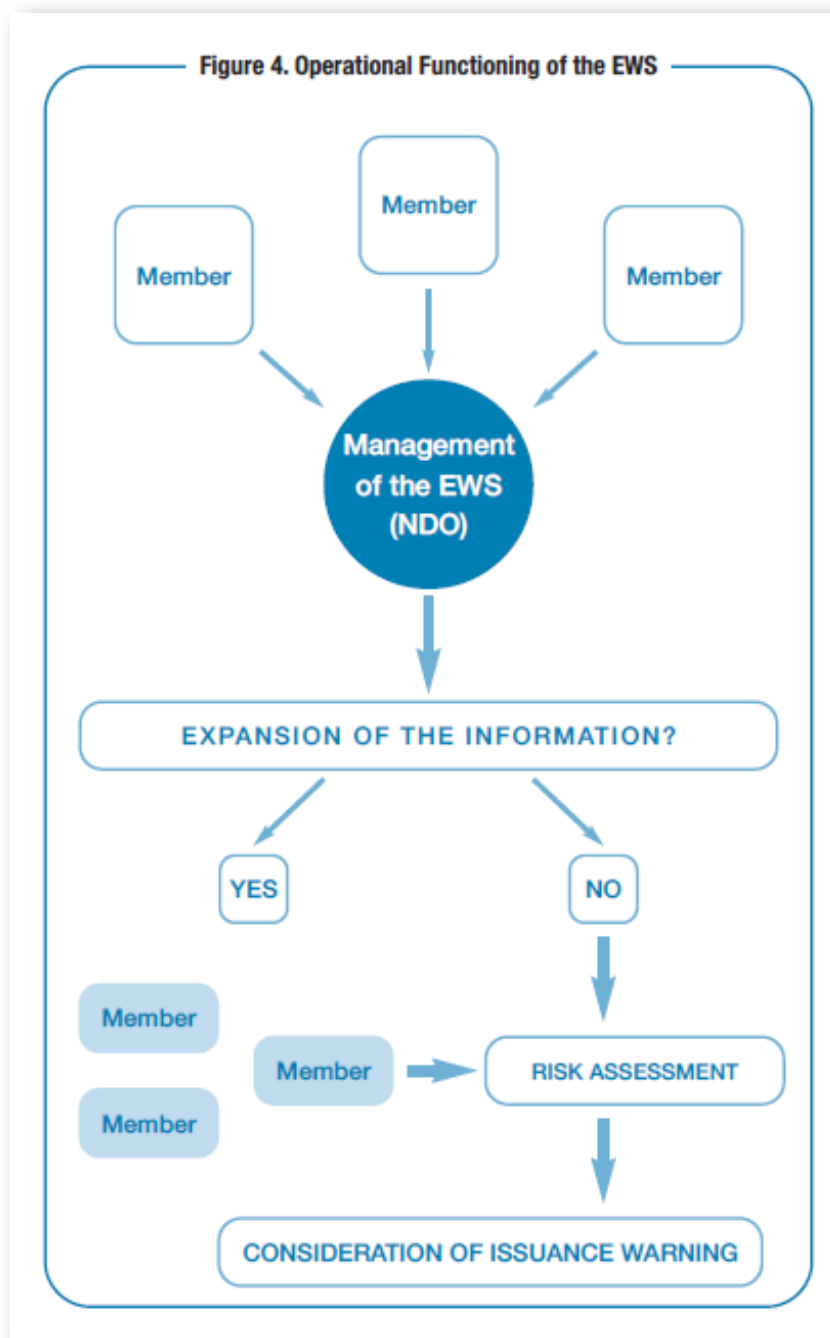
4.4 Fourth Step: Defining the operational structure

Once the stakeholders and roles of each institution have been identified, it becomes feasible to propose a functional scheme for the Early Warning System (EWS). This scheme must then be validated by all participants. Most existing EWSs operate within four phases, as presented in the diagram below, or some adaptation thereof:

- **Detection:** The system's members must provide information on new events, such as the discovery of new substances in street seizures or samples, associated toxicology, poisoning, or overdose cases, forensic or toxicological reports, key informants, and general population. This includes any means the system has for gathering information, like public complaints.
- **Classification:** At this stage, the network activates as information exchange begins. It is essential to supplement the information with the chemical classification of the detected substances. In cases of poisoning, overdose, and toxicological instances, the timely collection of biological samples for confirmation and identification of the consumed substance and its association with symptoms and adverse effects is crucial. However, the absence of chemical confirmation should not prevent cases from being tracked. Communication with other system members is required to contribute to or be informed about the case assessment.
- A range of **good practice manuals** on substance identification and results interpretation using various analytical techniques is available in the literature. This includes the Analytical Manuals of the European Customs Laboratory Network, the Analytical Manuals of the European Project, Response, the recommendations of the Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG), methods recommended by UNODC, and the European Network of Forensic Science Institutes (ENFSI).
- **Validation/Confirmation:** This involves the collection and analysis of relevant data and the triangulation of information from diverse sources. Data collection is a key step and needs expansion if the initially collected information is insufficient or unclear. Based on the system's criteria, the final identification of New Psychoactive Substances (NPSs) or emerging drug phenomena will be conducted.
- **Assessment of Associated Risks:** Once a new event is identified, a phase of rapid risk assessment associated with this phenomenon is activated. This uses previously collected information, new data,

and expert knowledge from the system's participants. Coordination is vital in this information exchange. The substance and event's characteristics and risks, and possible categorization of the phenomenon, are determined at this stage. The "Management and Maintenance of the Early Warning System" chapter in this manual further develops content on Risk Assessment.

- **Issuance of Warnings:** When the risks of the phenomenon have been assessed by system members, a warning is issued. The communication of risks associated with validated/confirmed phenomena is the *raison d'être* of the EWS; generating warnings justifies the EWS's existence. Warnings may be issued to different audiences depending on their content and scope (target population). The choice of recipient determines the type of content provided and the strategy and method of dissemination.



Warnings are issued when:

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

4.4.1 Warnings: Definition & Basic Characteristics

The Early Warning System (EWS) plays a crucial role in raising awareness and communicating risks associated with the use of New Psychoactive Substances (NPS) and emerging drug phenomena. It is vital for these systems to have the capacity to inform various stakeholders about situations posing a public health threat.

A warning implies vigilance and attention. Thus, the issuance of a warning is linked to situations of special risk or significant threats in public health, specifically related to NPSs or emerging drug phenomena. The goal of a warning is to capture the attention of the recipients, highlighting the significance of an event or phenomenon that demands special vigilance, control, or precaution. For instance, it might be crucial to alert health services and specialized institutions about a particular occurrence that could have serious health consequences or risks. Therefore, issuing warnings is an essential task and justification for the EWS.

Once an event is reported to and validated by the EWS, coordination by the system's members, whether joint or independent, may trigger a warning about the matter. During the decision-making process, the event's severity or significance in terms of its impact on public welfare is assessed. A warning is expected to reflect those events or issues that, inherently, hold special relevance according to the EWS's criteria. While other events may be reported to the system and monitored for some time, they might not necessarily lead to a warning.

The warning should contain information about a special event and may originate from data provided by one of the EWS's members. Alternatively, it could be a more complex communication that compiles information from various members about the same phenomenon, thereby capturing different dimensions of the system. Wherever possible, it's advisable for the warning to adopt the latter approach. However, it's important to acknowledge that information will always be limited and some questions may remain unanswered. Nonetheless, certain events, due to their significance or potential impact, require disclosure to prompt action.

A warning might be confined to specific network members or extended to other external EWS stakeholders (such as health service representatives, institutions, and even the general public), depending on the severity of the situation and its potential impact.

The dissemination of warnings from the Early Warning System (EWS) varies depending on the target audience:

- a) To EWS network members (in any case).
- b) To professionals outside the EWS, such as drug reduction institutions, emergency rooms, toxicological services, and relevant civil society organizations (if the threat to potential users is substantial).
- c) To the general public, either broadly or regionally (if the threat to potential users is real or of great magnitude).

The process from internal report to public warning involves several steps:

- **Initial Report and Coordination:** When the EWS receives critical information (e.g., a death related to an unusual substance), the coordinating entity shares this with system members, requesting additional details. The entity then collects and updates information for EWS members.
- **External Collaboration:** If further information is deemed necessary from outside the EWS network, the coordinating entity contacts external institutions for support. This stage involves discussing the situation within the EWS network and the National Monitoring and National Information and Analytical Centres or national drug coordinating institutions. If beneficial for drug user care programs (to prevent associated harm), the information is disseminated as a structured warning, initially targeted at specific institutions and programs, not the public.
- **Broader Dissemination:** The mass media, internet, or social networks are considered as last resorts for warning dissemination. However, the information validated by the EWS should also reach health stakeholders at various levels to enhance their practices.
- **Technical Independence and Objectivity:** The EWS must maintain technical independence to ensure that warnings are not influenced by external interests, such as political agendas.
- **Communication Strategy:** Developing appropriate communication products ("warnings") for intended recipients involves selecting suitable forms, content, and channels for maximum impact. The content may range from brief information to detailed documents, varying by medium and audience.
- **Process and Evaluation:** Issuing a warning involves evaluating multiple aspects. It requires a detailed analysis of the information's quality, safety, accuracy, and thoroughness.
- **Communication Plan:** The plan should consider the "how" and "what" of communication, anticipating questions from both specialists and the general public. Providing communication tools for addressing these queries is crucial.
- **Direct Communication Channels:** Offering direct communication channels within the EWS, especially for clinical or toxicological perspectives, can be beneficial.

Verification List of Information to Include in Warnings

What	Detail the nature of the event. What is occurring, and what is the potential public health threat?
Who	Identify the group of drug users affected. Which demographic is at risk?
When	Specify the date of the warning issuance. When was the threat identified, and how long has it been present?
Where	Describe the spatial scope. Is it a national issue, or confined to a specific region or city?
Why	Explain the cause of the problem and its threat to public health.
How	Provide recommendations for minimizing risks and preventing harm at the individual level. Include instructions for institutional representatives on responding to the alert and cooperating in communication efforts related to the alert's subject.

When directed to system members, the warning should be a structured document, and should contain the following information (if available):

- Nature of the warning, with a detailed description of the available information.
- Identification of the substance: Name of the chemical substance, including the molecule name, synonyms, abbreviations, and street names.
- Chemical Group: Classification of the substance's chemical group (e.g., aminoindans, arylalkylamines, arylcyclohexylamines, benzodiazepines, synthetic cannabinoids).
- Effects on humans: Documented effects, as described by drug users or in literature.
- Risk of abuse and dependence potential: Information on the substance's addiction potential, if available.
- Date of formal notification: Information on the first international notification and country-specific notification.
- Information on seizures by supply control authorities.
- Reported cases of non-fatal poisoning related to the substance.
- References: Links to relevant sources like scientific articles, meta-analyses, or press articles, if possible.

4.4.2 Public Warnings

When issuing public warnings, careful analysis and evaluation are crucial, considering the severity and potential escalation of the threat. Mass media, internet, or social media should be the final options for dissemination. The EWS's coordination unit must manage the release of information to the media.

The decision of recipients regarding any information will be influenced by the nature and severity of the monitored or reported phenomenon, as well as by general information available.

This will determine the communication approach, aiming to achieve the objectives of issuing a "warning" without causing "alarm."

This strategy helps avoid undesirable or counterproductive effects.

While "warning" involves active surveillance and communication about a specific event or phenomenon, "alarm" could lead to situations of panic or media mismanagement, potentially causing more harm than intended.

Selecting the appropriate communication medium and considering the potential unintended impacts or consequences is vital. The goal is to provide necessary information without arousing curiosity in non-users or promoting the substances. Balancing risk reduction communication and avoiding unintended consequences is a challenge. Descriptive terms like 'potent', 'strong', 'deadly', and 'toxic' could inadvertently attract interest in the substances.

Key elements of public warnings include:

- The nature and detailed description of the warning (what, who, when, how much, why).
- Context-specific risk description (the real threat).
- Practical advice on actions to take and avoid.
- The warning's issuance date.
- Issuer and contact details.

These warnings should also:

- Be tailored to specific target or at-risk groups (e.g. injecting drug users, party-goers, clubbers, the LGBT community).
- Use simple, clear, and consistent language.
- Summarize current information.
- Be geographically specific to reach only those at risk.

- Include messages about understanding risks, threats, and consequences.

Offer recommendations for detection, diagnosis, risk minimization, and addressing adverse consequences.

- Provide instructions for contacting the EWS unit.
- Include links and references for further information.
- Utilize credible channels and respected organizations for dissemination.
- Choose communication methods suited to the nature of the public health threat.

Before making warnings public, validate information quality through verifiable sources. Consider the balance between information quality and the urgency of warning the public. Post-dissemination, it's important to gather feedback on the warning's accessibility, interpretation, and effectiveness among target groups.

Details regarding the psychoactive effects of drugs should not be disclosed to the public to prevent increasing the likelihood of experimental use

4.5 Fifth Step: Implementing the Early Warning System

The crucial moment in implementing the Early Warning System (EWS) is for members to validate and reach a consensus on the operating delivery and information exchange system. This ensures all members understand and agree on the system's operation and the data exchange format.

Initial meetings between the EWS's coordination unit and members should formalize the system, with institutions and stakeholders commencing active monitoring. These meetings are also crucial for validating the operational framework and data collection tools, and for determining the specific events or phenomena each member is responsible for reporting.

A basic list of events for the EWS to report includes:

- Identification of New Psychoactive Substances (NPSs) from seizures or other sources, and biological samples.
- Deaths directly or indirectly associated with NPSs or other drugs.
- Non-fatal intoxication cases from NPSs or other drugs requiring medical assistance or hospitalization.
- Adverse effects linked to NPSs or known drugs.
- Production of NPSs in the country.
- Cases identifying NPSs as diluents or adulterants in other major drugs.

- Cases with unusually high active substance concentrations in known/common drugs.
- Presence of dangerous adulterants in known/common drugs.
- New patterns of drug use increasing health risks.

Rapid reporting of these events is vital for the EWS's effectiveness, with the goal being prompt notification, even if initial information is incomplete. The shorter the time between an event's discovery and its reporting to the EWS, the more efficient and impactful the system can be in issuing warnings and implementing public health measures.

It is recommended that a periodic reporting schedule be established for each stakeholder, even for confirming the non-occurrence of monitored phenomena. This regular communication, such as monthly updates stating "No new event to report," ensures continuous surveillance and consistent communication within the EWS.

4.6 Pilot Exercise to Validate the Operation of the Early Warning System

A practical way to test the Early Warning System's (EWS) functionality is through a simulation exercise. A meeting or workshop with EWS members can be conducted where a hypothetical case is presented and role-played to examine and revise each operational step. The exercise concludes with a review session to discuss outcomes, provide feedback, and suggest adjustments.

Case Study	
<i>In country "X", a drug treatment centre receives a report from a young man who suspects he was sold "Krokodil" (Desomorphine, an opioid) instead of heroin, due to severe skin irritation and unusual symptoms post-injection.</i>	
Detection Phase	The treatment centre reports this event to the EWS's coordination unit (National Monitoring and National Information and Analytical Centres), initiating the process.
Characterization and Event Confirmation Phase	The coordination unit must confirm the presence of "Krokodil" in the country, primarily through lab examination of the young man's fluids or obtaining and analysing a street sample. In this scenario, the treatment centre's lab confirms "Krokodil" use through blood sample analysis.
Information Collection	Important information includes the sample presentation, packaging characteristics, sample photography, place, and date of discovery. Additionally, research on the substance's health effects, toxicity, pharmacology, clinical manifestations, risks, associated damage, and international incidents is necessary.
Risk Assessment Phase	Analysing the collected data helps evaluate the risks and decide on issuing a warning. In this case, after assessing the severe poisoning risks, a decision is made to issue a warning about "Krokodil".
Issuing Phase of Warnings	The warning is crafted and disseminated, tailored to specific recipients. In this example, it's crucial to alert heroin users in the area where "Krokodil" is marketed, as well as inform health sector and police authorities to prepare for emergencies and control measures to reduce the substance's availability.

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/>

5. Management and Maintenance of Early Warning Systems

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 a Coordinating Body/Unit/Institution 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.

5.1 Priority Tasks for the Early Warning System's Coordination

Network Monitoring and Maintenance and Platform Management: which involves evaluating the incorporation of new members and taking the necessary steps in this regard. Refer to Chapter 2 for guidance on contacting institutions and organizing their meetings. In the case of EWSs equipped with a computer platform and access limited to previously registered users, the coordination unit should manage access for new participants. Additionally, they should provide any necessary advice for the effective management of the platform.

Stimulate Member Participation, whose primary role is to share relevant information aligned with the objectives set by the EWS. Members should also contribute to expanding information on events reported by other members and participate in various activities organized by the EWS's coordination. To achieve this, it is crucial to keep all members engaged and informed about relevant issues, highlighting the usefulness and benefits of the EWS. Involving them in different stages of the EWS's processes and final outputs is also essential.

Validate the received information through triangulation, aiming to identify actual trends and events relevant to the EWS. This involves ensuring data completeness and adhering to established protocols. By soliciting further information from members and stakeholders, including consultants or international bodies, the EWS strives for factual accuracy.

Network Activity: Keep the network active by continuously circulating information, including reports from members and the EWS coordination. This encompasses sharing research findings, scientific articles, and updates from international organizations.

Communication Tool Development: Develop communication tools with system members for various audiences, such as health and drug treatment centres, professionals, drug users, and the general public. Disseminate warnings prepared by the EWS to relevant stakeholders, including decision-makers and healthcare providers.

Dissemination of Warnings: Ensure that warnings prepared by the EWS are disseminated to appropriate stakeholders, including decision-makers, clinical settings, supply control agencies, healthcare centres, and the general public.

Political Sensitization: Maintain awareness among political bodies to support the EWS mandate..

Monitoring External Information Sources: Monitor additional information sources like media, social networks, and specific Internet/Darknet sites for insights into emerging drug phenomena and market

trends. This web monitoring, though challenging, is essential for gathering comprehensive information. Numerous internet portals, many specializing in the field of drugs, along with user forums and social networks, offer a broad spectrum of information on drugs.

Monitoring these portals is crucial as they are created by users themselves and serve as platforms for accessing substances, discovering new market items, and adopting specific consumer practices, including both new and resurgent ones.

In these spaces, practical care guidelines are often shared, which may not always be appropriate. Therefore, web monitoring is essential for the EWS, providing rich information. However, it differs from other sources as it requires careful coordination and diligent monitoring of communication channels to extract and share relevant information within the network.

Promote Research Projects: Encourage research projects and activities that provide insights into the phenomena addressed by the EWS. These should be ad hoc studies involving EWS members, focusing on specific aspects of the subject.

5.2 Other Tasks in Coordinating the Early Warning System

The coordination of the Early Warning System (EWS) involves several crucial tasks beyond its basic operation:

System Update and Maintenance: For EWSs operating on computer platforms, the coordination unit should oversee their updating and maintenance, ensuring they meet the system's specific needs.

Periodic Meetings: Organize regular meetings with EWS members to discuss specific topics or new findings relevant to the EWS. These meetings can include a segment of members or the entire membership.

Developing EWS Outputs: Apart from issuing warnings, the EWS should also develop and update other outputs like databases, bulletins, and global reports that describe and analyse drug trends.

Information Exchange: Promote and facilitate information exchanges with national and international EWSs and organize events such as meetings, symposia, and conferences on the subject. These events provide a platform for information exchange, updating membership, and increasing EWS visibility.

Capacity Building: Encourage and enhance the capabilities of members through ongoing education. It's crucial to promote and support these bodies, fostering the development of members in their respective areas with topics relevant to the EWS. After analysing the drug phenomenon in a specific country and engaging with various stakeholders, challenges will inevitably arise.

Creating an EWS and its integration with different institutions presents an ideal opportunity to address these training needs. The UNODC has identified multiple challenges due to the spread of NPSs across various sectors, including health services, forensic drug labs, law enforcement, regulatory agencies, and legal departments. For instance, forensic labs may struggle to identify NPSs in drug or biological samples. Law enforcement might find it challenging to detect new substances on the streets. Legal authorities could be unfamiliar with the appropriate legal measures for controlling the production and trafficking of NPSs. Health services may lack the preparation to identify or respond to NPS usage if they are not knowledgeable about their effects and pharmacology.

Recommended Topics to Sensitize and Train Members of the EWS

- The Challenges of NPSs and Emerging Global Drug Phenomena
- Global Trends in the Use and Spread of NPSs
- The Dynamics of Production and Trafficking of NPSs
- Evolving Drug Markets and Changes in Drug Policies
- Legislative Measures for Controlling NPSs
- Patterns of Consumption and the Effects of NPSs in Emerging Drug Trends
- The Impact of NPS Consumption on Public Health
- Strategies for the Detection, Care, and Reporting of NPS Incidents in Health Services
- Techniques for the Detection of NPSs in Laboratory Settings
- The Significance of Adulterants in NPS Detection
- Methods for Identifying NPSs in Biological Samples
- Monitoring and Surveillance Strategies for NPSs and Emerging Drug Trends
- Public Health Responses: Prevention, Risk Reduction, Harm Reduction, and Treatment Strategies for Drug Users

5.3 Information Flow: Detection and Risk Assessment

Initial Reporting: Information circulation within the Early Warning System (EWS) starts with the reporting of events by any member, using various formats based on relevance and urgency.

Detection of NPS or Emerging Drug Phenomena: Members report the identification of New Psychoactive Substances (NPS) or related events like unusual adulterants, rare drug seizures, health issues linked to known drugs, or high potency drugs. A standard report form is used for these cases, even if the information is initially incomplete.

Data Verification: The coordination unit reviews each report to verify the data, especially determining if the substance or event is previously known or a new identification in the country. Incomplete reports are checked to assess whether missing data is simply omitted or truly inaccessible. The unit also determines if the provided information is enough to trigger the action protocol or if additional details are needed.

Information Circulation Methods: The EWS may use different models for circulating information. Some systems centralize, analyse, evaluate, and validate reports before sharing them with the network. In contrast, others may share initial reports directly with all members without prior analysis.

Additional Information Gathering: When initial reports are insufficient, the coordination unit may request more details from the reporting member or other experts. This can include consulting external sources like international portals or research reports.

Risk Analysis: Once adequate information is obtained, a rapid risk analysis is conducted. The National Monitoring and National Information and Analytical Centres should maintain constant communication with EWS members for a comprehensive assessment of the event, considering all related health and social risks.

Response to Serious Threats: The EWS monitors and responds to high-risk events, such as fatal or serious intoxications. If adverse health events increase, the EWS may issue alerts to specific stakeholders like drug user services, treatment centres, or emergency medical facilities.

Criteria for Serious Cases: The seriousness of an event is assessed based on various criteria, including the quantity of material seized, evidence of international trafficking, organized crime involvement, pharmacological and toxicological properties of the substance, potential for rapid dissemination, cases requiring medical attention or hospitalization, and evidence of deaths.

5.4 Risk Assessment Process in the EWS

Initiation: When a high health threat probability is reported, the EWS coordinating unit rapidly gathers information from its members and other relevant entities, tailored to the nature of the threat.

Assessment Focus: The assessment includes evaluating the health risks to drug users, social costs, and the likelihood of the threat spreading. It also considers potential therapeutic or economic benefits of the emerging drug, as per EU practices.

Data Quality and Sources: Due to the variability in the availability and quality of information on emerging drugs, priority is given to higher quality data. However, the value of less scientifically rigorous data is also recognized (EMCDDA, 2009).

Data Collection Areas: Ideally, the collection covers:

- Chemical and physical descriptions, including user-known names.
- Usage frequency, circumstances, and quantities.
- Manufacturing methods and means.
- Trafficking details.
- Health and social risks.
- Prevalence and patterns among various user groups.
- Current assessment status by international bodies.
- Applicability of national, EU, or international control measures.
- Chemical precursors used in manufacturing.
- Mode and extent of the new substance's use.
- Other uses and commercial authorization status.

Balancing Timeliness and Thoroughness: The assessment should be quick yet thorough to ensure a balance between collecting adequate information and enabling rapid response.

Outcome: Following the risk assessment, a tailored warning may be issued, considering the specific issues and the target audience.

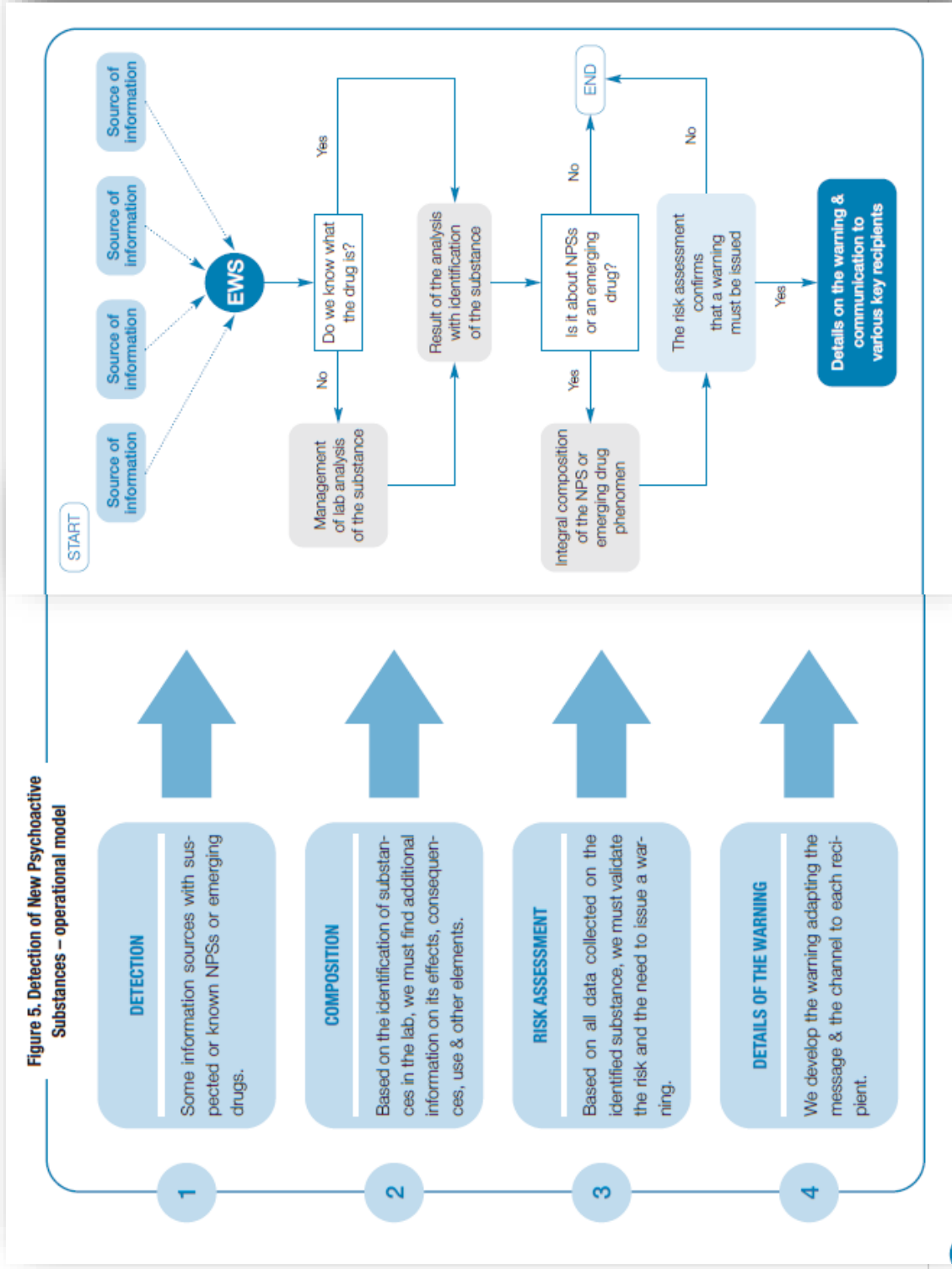
Risk Assessment: When a high probability of health threats arises from a reported event or phenomenon, the EWS's coordinating unit swiftly initiates information collection through its members and relevant entities, tailored to the threat's nature. This assessment phase evaluates potential risks to drug users' health, social costs, and the likelihood of the threat spreading across populations. The potential therapeutic or economic benefits of emerging drugs are also considered as per EU practice.

Data collection and analysis should align with national and international scientific evidence. Despite the limitations of emerging drug phenomena, such as limited data availability and varying data quality, priority is given to higher-quality data, acknowledging the value of less rigorous data (EMCDDA, 2009).

Key data collection areas include:

- Chemical and physical descriptions of the drug, including user-known names.
- Frequency, circumstances, and quantities of drug usage.
- Manufacturing methods and means of the drugs.
- Trafficking information.
- Health and social risks.
- Prevalence of use among various population segments, user characteristics, and usage patterns.
- Assessment status by the EU or UN.
- Drug identification at the EU or international level.
- Applicability of control measures at various levels.
- Chemical precursors used in manufacturing.
- Mode and extent of the new substance's use.
- Other uses of the drug and the extent of such use.
- Commercial authorization status of the drug.

Risk assessment must be conducted efficiently to balance thorough information gathering with the need for a rapid response. Following this assessment, a warning may be issued based on the collected data, tailored to the communication needs and target audience.



5.5 Instruments for Data Collection and Exchange in the EWS

Standardized Tools: Utilizing standardized tools for internal communication among EWS members sets clear guidelines on the dimensions and variables to be communicated. These tools streamline the organization and processing of data in each report, enhancing the system's efficiency.

Data Collection and Exchange: It's recommended to adopt or adapt international reporting tools for effective information exchange. These include forms like the Identification of NPS and Emerging Drug Phenomena, adapted from the EMCDDA-Europol form, and the Adverse Health Event Reporting Form.

Report Forms: The Identification Report on NPSs or emerging drug phenomena and the Adverse Health Events Report can be in the form of a questionnaire using text or spreadsheet editors. Spreadsheet files are beneficial for combining reports or loading them into statistical software.

Report Form on Identification of New Psychoactive Substances or Emerging Drug Phenomena: This form is essential for EWS members to report relevant information, such as occurrences in biological samples or significant seizures. It includes various details like authority reporting, date of detection, substance names, source, physical description, market extent, price, purity, use patterns, effects, usage context, risks, and organized crime involvement.

Adverse Health Event Report Form: This form is used for reporting serious intoxications or fatal cases related to NPSs, other drugs, adulterants, or diluents, usually by toxicological labs or health centres. The form should cover information like the reporting agency, event date, type of event, victim's demographics, sample types analysed, analysis methods, results, substance information, symptoms, and any links to other cases.

Other Stakeholder Reports: Health states and consequences related to NPSs or other drugs can also be reported by NGOs or police. However, these reports, often based on subjective drug user accounts, are typically communicated through more informal channels.

5.6 Dissemination of Information from Early Warning Systems

Effective information generation and communication are crucial functions of the Early Warning System (EWS). A key challenge for the EWS is its ability to report information in a timely manner. Relevant event information should be:

- Shared with authorities and institutions handling supply control to bolster controls and interdiction efforts.
- Communicated to health sector institutions and stakeholders to prepare them for potential demands on health and social services.
- Disseminated to organizations involved in prevention, risk, and harm reduction.

For successful communication, the EWS needs to develop various products tailored to each communication objective. This development depends on the intended recipient, the chosen communication channel and the specific message to be conveyed. Key considerations include:

- What is the message to be communicated?
- How should it be communicated?
- Who is the target audience for the communication?

5.7 Recipients/Beneficiaries of the Early Warning System's Outputs

- (a) **Decision-makers:** Disseminating EWS information and products to authorities or stakeholders involved in decision-making for drug demand and supply control policies is crucial for evidence-supported public policy.
- (b) **Health Care Professionals/Experts:** Timely information from the EWS is essential for clinical professionals across various healthcare settings. Knowledge about substances, their usage patterns, effects, toxicity, and history of poisoning or overdose aids in more accurate diagnoses and effective treatments.
- (c) **Interdiction Forces:** These forces benefit from EWS information on the chemical characterization of substances, their morphological characteristics, user-provided information, marketing, and distribution methods.
- (d) **Drug Users:** Drug users, particularly of synthetic drugs and NPSs, need information on chemical composition, dosage, and associated risks to adopt safer use practices and harm reduction measures.
- (e) **General Population:** EWS information is valuable for the general public, including family and friends of drug users, providing insights into care and actions in case of acute intoxication. It also contributes to public awareness and destigmatization of drug users.
- (f) **Other Countries:** Given the global nature of NPSs and emerging drugs, international epidemiological surveillance is vital. Access to warning information from other countries helps in timely preventive measures.
- (g) **International Organizations and Programmes (UNODC, EMCDDA, CADAP, etc.):** These bodies monitor global drug phenomena, gather information, and conduct analyses. Access to national EWS data enriches their regional and global analysis, aligning with the objectives of the Commission on Narcotic Drugs Resolution 57/9 to detect, analyse, identify NPSs, and share best practices for demand reduction and treatment.

5.8 Outputs of the Early Warning System

The Early Warning System (EWS) generates various products through the analysis and validation of information from its members.

Warnings: The primary output of the EWS is warnings, which communicate risks associated with validated or confirmed phenomena. These are vital for the EWS's purpose, as detailed in Chapter 2 of the Manual.

Risk Assessment Reports: These documents detail the findings and conclusions from the risk assessment phase, disseminated to EWS network members.

Database: A structured system storing reported information for advanced processing. It contains comprehensive data on NPSs and other drugs, including:

- Dates of substance identification and reporting.
- Details of detection, including the case number, place, and circumstances.
- Reporting authority and sample type.

- Substance details, including names and chemical group.
- Physical form, quantity, and market information.
- Risk analysis from health and social perspectives.
- Control measures and consumption methods.
- Additional notes related to the case.

This database, managed by the EWS's coordination unit, is electronically accessible to network members, with editing restricted to the coordination unit.

Protocols for Action: EWSs can generate specific action protocols for clinical, forensic, and other areas, especially when new procedures are proposed following the confirmation of a NPS or emerging drug.

Bulletins/Reports: Regular reports or newsletters can reflect cumulative reporting by system members or a collection of EWS-issued warnings. Special reports on particular themes and methodologies like Trendspotting⁵ are also developed.

Ad Hoc Studies: The EWS encourages proposals for specific studies focused on emerging drug phenomena, often involving network members.

Summary Report: An annual report providing an overview of the situation concerning NPSs, emerging trends, adverse events, EWS network evaluations, and legislative developments. It may include aggregated data on NPS identifications in different sample types.

Reports to International Organizations: For significant international findings, the EWS's coordination unit should report to supranational organizations like UNODC, CICAD/OAS, and EMCDDA. Information on substances identified at the European or international level is accessible through databases like EDND and EWA, managed by EMCDDA and UNODC, respectively.

⁵ Mouteney, J. (2016). Trendspotting Approaches: Using Mixed Methods to Explore Emerging Drug Phenomena. EMCDDA

Acronyms

CADAP	Central Asian Drug Action Programme
CARICC	Coordination Centre for Combating illicit trafficking of Narcotic Drugs, Psychotropic Substances and their Precursors
CICAD	Comisión Interamericana para el Control del Abuso de Drogas
COPOLAD	Cooperation Program between Latin America, the Caribbean and the European Union on drug policy
DRID	Drug– related infectious diseases
DRD	Drug– related deaths
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EU	European Union
EWS	Early Warning System
MIA	Ministry of Internal Affairs
MoH	Ministry of Healthcare
NDEWS	National Drug Early Warning Systems.
NPS	New psychoactive substances
NSP	Needle and syringe programme
OAS	Organización de los Estados Americanos
OFDT	Observatoire Français des Drogues et des Toxicomanies
OST	Opioid Substitution Treatment
PWID	People Who Inject Drugs
PWUD	People Who Use Drugs
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organisation

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, and taste (e.g., blending cocaine with sugars, talc, or mannitol).

Early Warning Systems: A multi-disciplinary, interagency network formed by key stakeholders that generates and exchanges 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 diluents detected), behavioural changes, or changing consumption patterns which could potentially lead to new risks for public health.

New Psychoactive Substances (NPS): These are a group of psychoactive substances, the majority of which are synthetic in origin, but can also be of vegetable origin, medical or veterinary products that are not found in the list of controlled substances according to the 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 supplements.

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.

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Deliverable 3

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Deliverable 3

UNODC Laboratory and Scientific Service Portals – January 2022 – UNODC-SMART: 1,124 NPS reported to UNODC from 134 countries and territories - NPS reported to UNODC each year, by substance group, 2009-2021

Available at: <https://www.unodc.org/LSS/Announcement/Details/40df1bf0-4f70-4862-844e-20536e0d95fd>

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Annex I - Key Information on NPS 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 an expanding global phenomenon 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."

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 analysing 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.

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

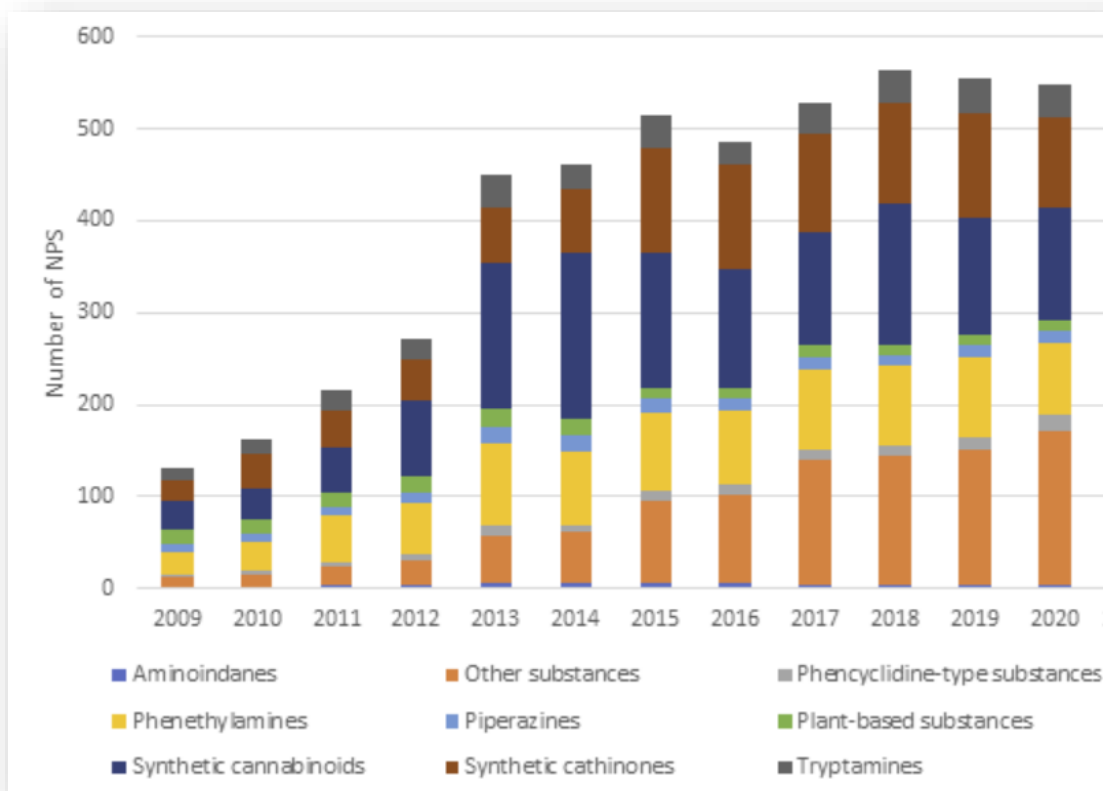
NPSs or emerging drug phenomena represent a diverse group of substances that are produced clandestinely; they seek to emulate and surpass the effects of substances of natural origin, and produce new ones by a variation in their chemical structure. In this way, they circumvent regulatory controls to which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

UNODC has identified 9 groups of NSPs 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.

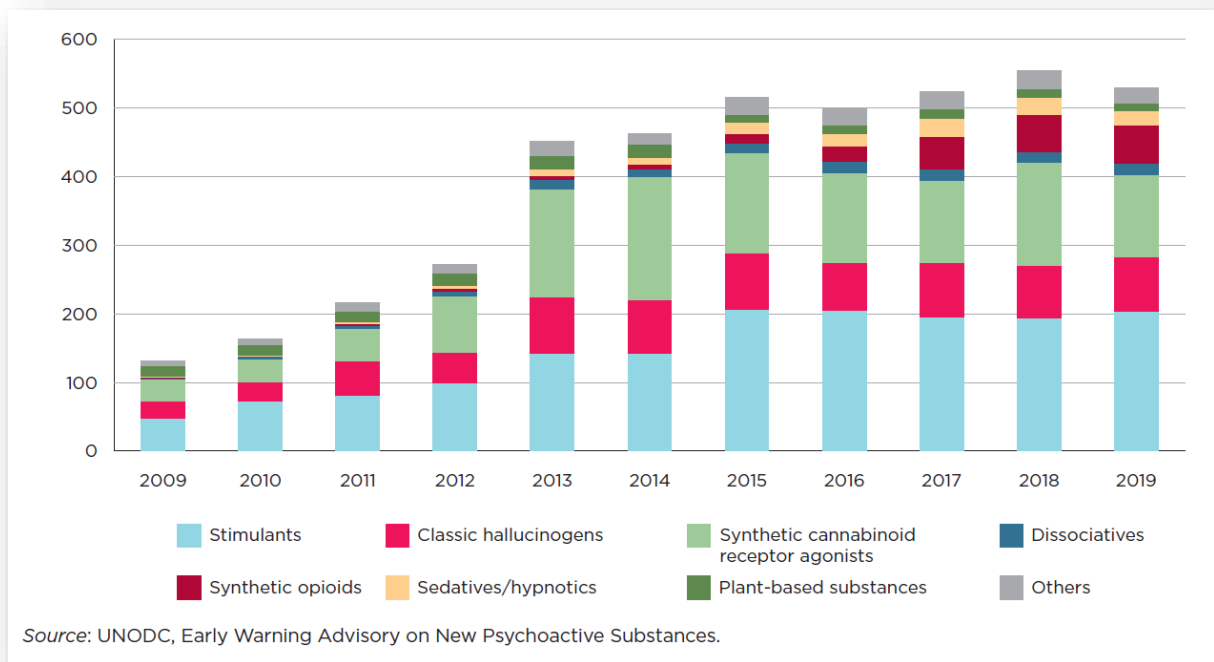
New psychoactive substances reported to UNODC each year, by substance group, 2009-2021



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

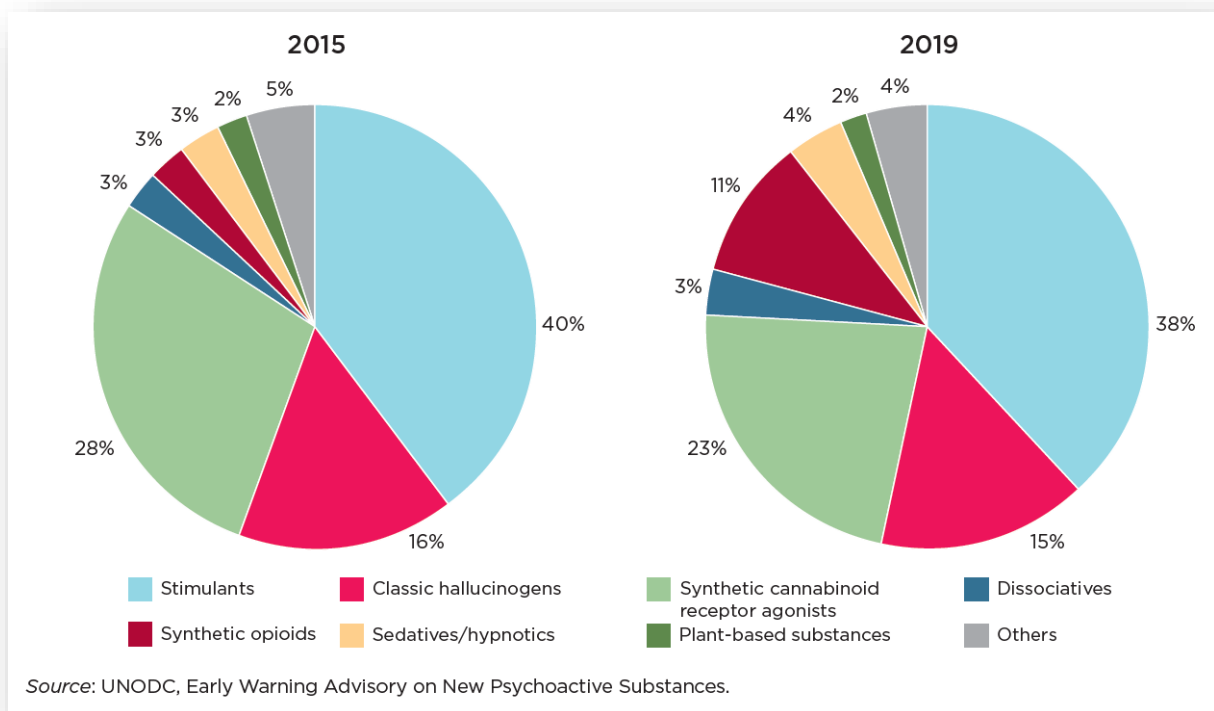
Another form of classification of NPSs is based on the pharmacological effects that they produce. This aspect is fundamental; it happens that substances with similar chemical structure produce different pharmacological effects, yet, on the contrary, a similar effect can be produced by a NPS of dissimilar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

Early Warning Advisory on New Psychoactive Substances (UNODC)



This classification is reflected in the graphs below and shows the largest group of stimulants which comprise 38% 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.⁶

⁶ https://www.unodc.org/unodc/en/scientists/2020-global-synthetic-drugs-assessment_Global.html



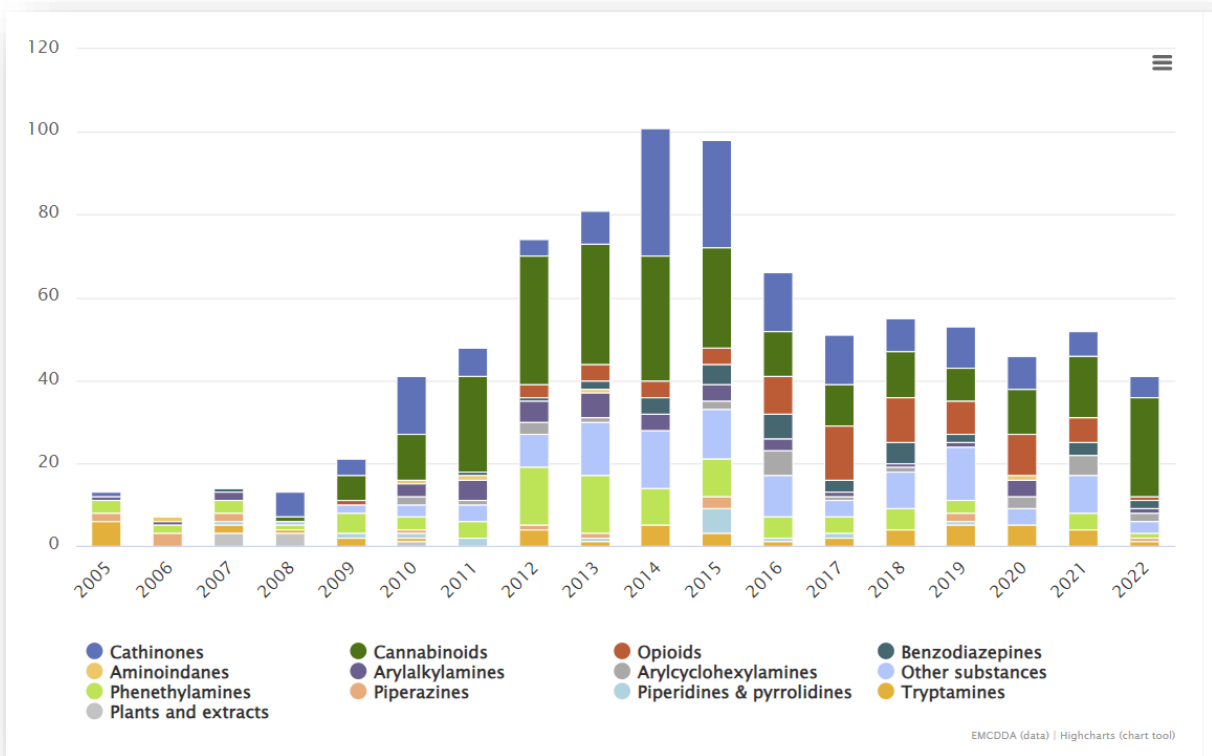
Finally, from a legislative perspective, new psychoactive substances are characterized as follows:

- 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.

EMCDDA uses the following classification of substances within EU EWS:

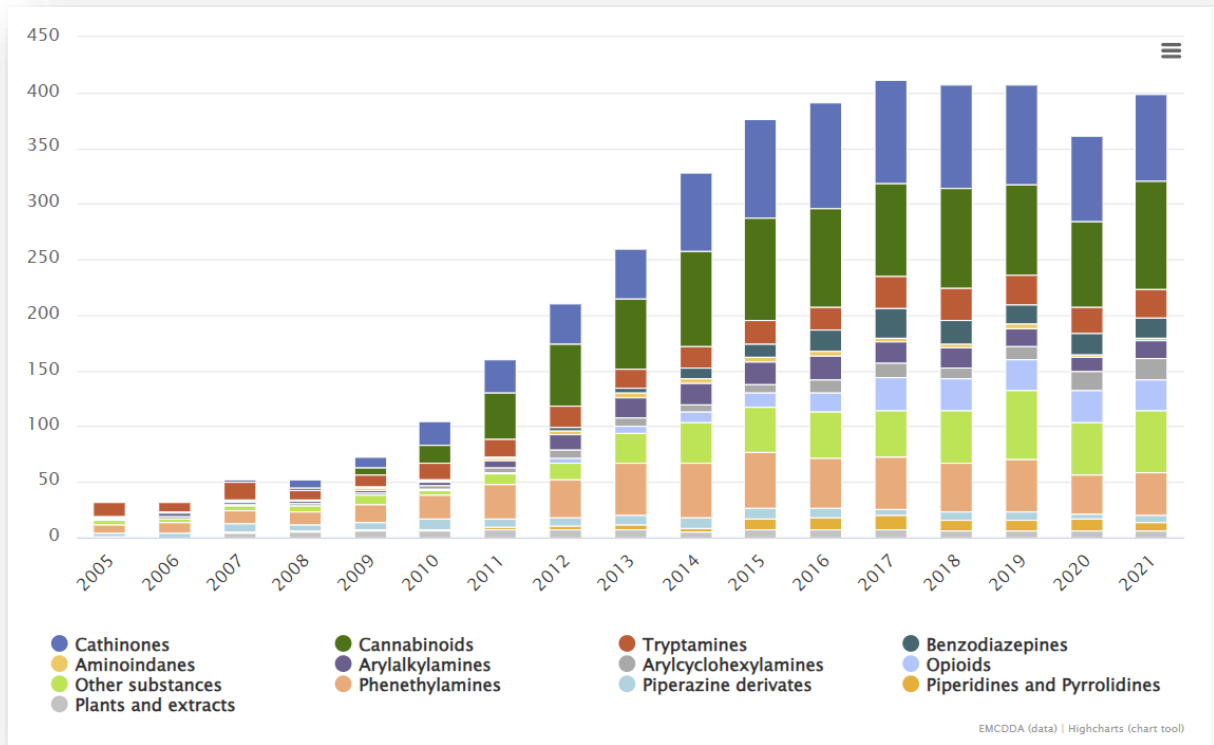
- Aminoindanes
- Arylalkylamines
- Arylcyclohexylamines
- Benzodiazepines
- Cannabinoids
- Cathinones
- Plants & extracts
- Indolalkylamines (tryptamines)
- Opioids
- Others
- Phenethylamines
- Piperazine derivatives
- Piperidines & pyrrolidines
- Fentanils

Number of new psychoactive substances reported for the first time to the EU Early Warning System, by category, 2005–2022⁷



⁷ https://www.emcdda.europa.eu/publications/european-drug-report/2023/new-psychoactive-substances_en

Number of new psychoactive substances reported each year following their first detection in the European Union, by category, 2005–2021



Annex II - Description of EWS 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.

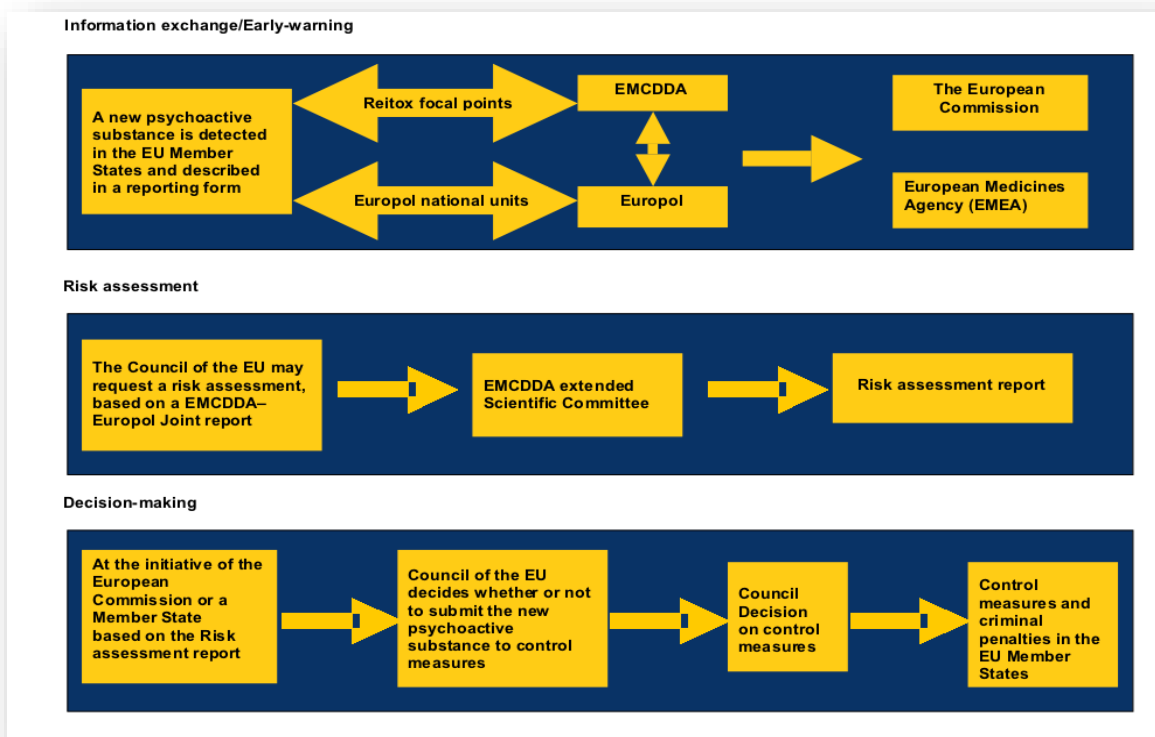
The Programme leads the way in developing what has been called Early Warning Advisories (EWAs) on NPSs. UNODC's New Psychoactive Substance Early Warning Advisory helps to identify NPSs for international re- view, taking into account geographical prevalence and persistence.

The European Union's Early Warning Systems (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 Council Decision 2005/387/JHA this three-step approach was maintained:



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).

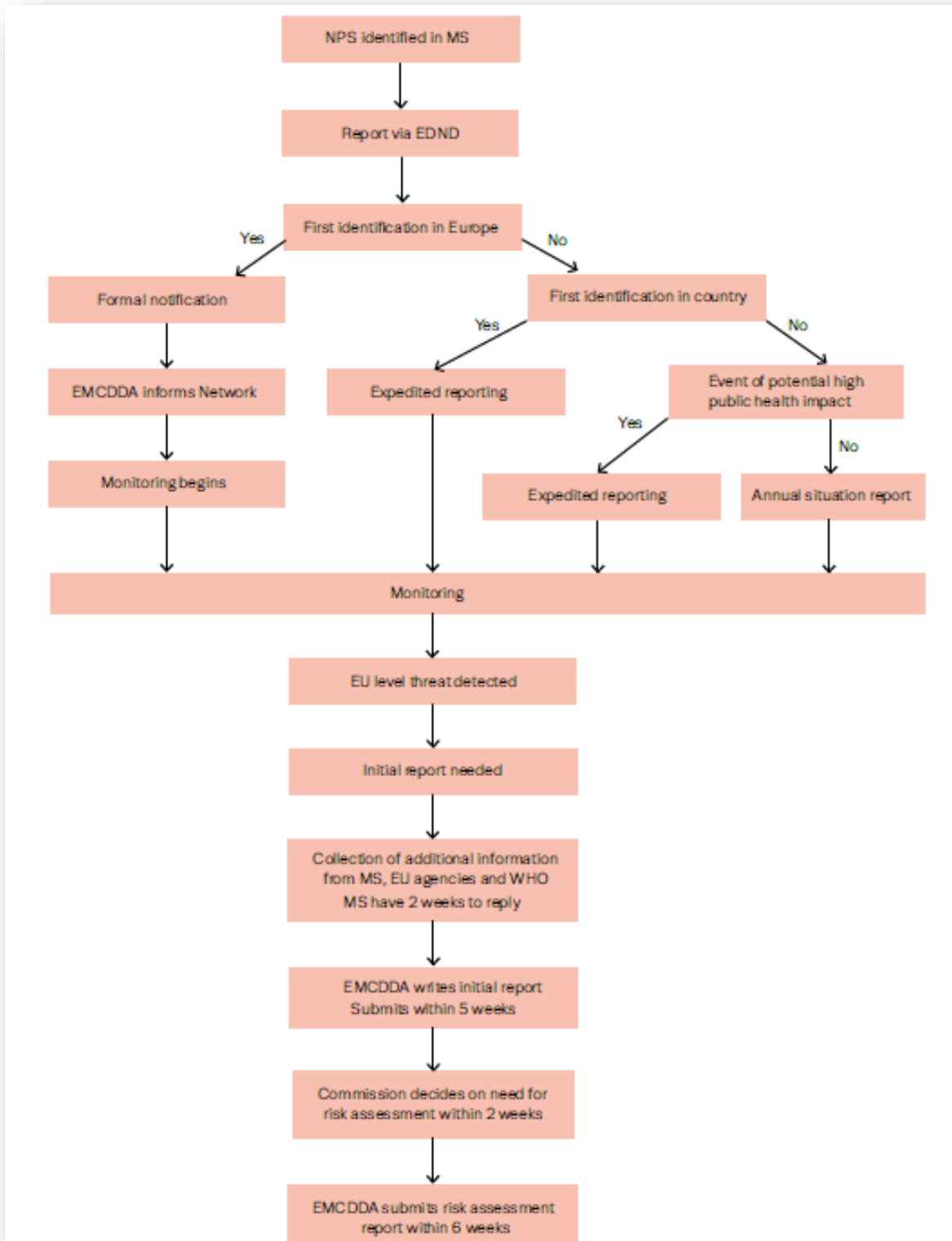
On this basis, if Europol and the EMCDDA consider that the information requires monitoring, a Joint Report is prepared and submitted to the Council of the European Union, the European Commission and the EMA.

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.

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 more than 950 substances that are monitored.

Within current Regulation (EC) 1920/2006 (as amended by Regulation (EU) 2017/2101), the EWS information flow can be defined as follows:

Information flows in the Early Warning System



After EMCDDA Risk Assessment report is submitted, the European Commission according to Council Framework Decision 2004/757/JHA (as amended by the Directive (EU) 2017/2103)⁸ initiates following steps:

1. Based on a risk assessment or combined risk assessment carried, the Commission shall, without undue delay, adopt a delegated act in accordance with Article 8a amending the Annex to this Framework Decision in order to add the new psychoactive substance or substances to it and provide that the new psychoactive substance or substances pose severe public health risks and, where applicable, severe social risks at Union level, and that it is or they are included in the definition of “drug”.
2. When considering whether to adopt a delegated act as referred to previous paragraph, the Commission shall take into account whether the extent or patterns of use of the new psychoactive substance and its availability and potential for diffusion within the Union are significant, and whether the harm to health caused by the consumption of the new psychoactive substance, associated with its acute or chronic toxicity and abuse liability or dependence-producing potential, is life-threatening. The harm to health is considered life-threatening if the new psychoactive substance is likely to cause death or lethal injury, severe disease, severe physical or mental impairment or a significant spread of diseases, including the transmission of blood-borne viruses.
3. In addition, the Commission shall take into account whether the social harm caused by the new psychoactive substance to individuals and to society is severe, and, in particular, whether the impact of the new psychoactive substance on social functioning and public order is such as to disrupt public order, or cause violent or anti-social behaviour, resulting in harm to the user or to other persons or damage to property, or whether criminal activities, including organised crime, associated with the new psychoactive substance are systematic, involve significant illicit profits or entail significant economic costs.
4. If, within six weeks of the date of receipt of the risk assessment report or the combined risk assessment report in accordance with Article 5c(6) of Regulation (EC) No 1920/2006, the Commission considers that it is not necessary to adopt a delegated act to include the new psychoactive substance or substances in the definition of “drug”, it shall present a report to the European Parliament and to the Council explaining the reasons for not doing so.
5. As regards new psychoactive substances added to the Annex to the Framework Decision, Member States which have not yet done so shall bring into force the laws, regulations and administrative provisions necessary to apply the provisions of this Framework Decision to those new psychoactive substances as soon as possible but no later than six months after the entry into force of the delegated act amending the Annex. They shall immediately inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Framework Decision or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017L2103>

National control measures

Without prejudice to the obligations imposed on the Member States under this Framework Decision, Member States may maintain or introduce in their territories, with regard to new psychoactive substances, any national control measures that they consider appropriate.

More information on legal approaches to controlling new psychoactive substances can be found in the EMCDDA's summary publication. This summary was also translated into Russian within CADAP 6 programme.

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Prepared by: Marisa Perelló MA

Reviewed by: Assoc. Prof. Viktor Mravčík, MD, PhD