



European Monitoring Centre
for Drugs and Drug Addiction

GUIDANCE NOTE 3

Information that should be reported by the Member States on a new psychoactive substance

EMCDDA operating guidelines for the European Union Early Warning
System on new psychoactive substances

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1. Purpose

The purpose of this document is to provide guidance on the types of information on a new psychoactive substance that the Member States should report under the terms of Article 5a of Regulation (EC) No 1920/2006 (as amended). The available information should be reported to the EMCDDA and Europol, taking into account their respective mandates, by the Member States through their national focal points and their Europol national units. The information should be reported in a timely manner and without undue delay.

The document provides a list that covers the main types of information required for the operation of the Early Warning System, as well as those required for the initial report and risk assessment, and to support decision making on control measures (Section 9). The list has been compiled based on the requirements of Regulation (EC) No 1920/2006 (as amended) and Council Framework Decision 2004/757/JHA (as amended). In particular the information is related to:

- detection and identification;
- use and patterns of use;
- manufacture or extraction;
- distribution and distribution methods;
- trafficking;
- commercial, medical and scientific use; and
- potential and identified risks.

The list is also informed by the practical experience gained and lessons learnt during the implementation of Council Decision 2005/387/JHA, with respect to accepted scientific principles and required scientific evidence. The list should not be regarded as a definitive list of information that should be reported by the Member States. The Member States may report any other type of information that they judge to be relevant. The specific data elements for each type of information are provided in the EMCDDA reporting tools, including the European Database on New Drugs (EDND).

The guidance provided in this document will not fit every possible situation perfectly, and may need to be adapted in order to effectively respond to a specific event or situation. In such cases, the Reitox national focal points should contact the EMCDDA for advice as soon as possible.

→ You can contact us at: ews@emcdda.europa.eu

2. Scope

This document applies to the Reitox national focal points and the EMCDDA.

3. Changes since last revision

Not applicable. Initial Guidance Note.

4. Responsibilities

It is the responsibility of the EMCDDA and the Reitox national focal points to ensure that this guidance is adhered to.

According to Article 5b of Regulation (EC) No 1920/2006 (as amended), each Member State shall ensure that its national focal point and its Europol national unit provide the EMCDDA and Europol, taking into account their respective mandates, with the available information on new psychoactive substances in a timely manner and without undue delay. The information should be related to the types listed in Section 9 as well as any other information that the Member State judges to be relevant.

5. Documents needed for this Guidance Note:

- EMCDDA Operating Guidelines for the European Union Early Warning System on New Psychoactive Substances

6. Related documents

- Regulation (EC) No 1920/2006 (as amended).
<http://data.europa.eu/eli/reg/2006/1920/2018-11-23>
- Council Framework Decision 2004/757/JHA (as amended).
http://data.europa.eu/eli/dec_framw/2004/757/2017-11-22

7. Terminology and definitions

- Guidance Note 1: Terminology and definitions

8. List of abbreviations

AND: Action on New Drugs

EDND: European Database on New Drugs

EMCDDA: European Monitoring Centre for Drugs and Drug Addiction

NEWS: National early warning system

NFP: Reitox national focal point

NPS: New psychoactive substance

9. Types of information that should be reported by the Member States on a new psychoactive substance

a) Detection and identification

This includes the available information on:

- Names and identifiers
 - Chemical name(s)
 - Common, code names, or trivial names
 - International non-proprietary names, official synonyms, and non-proprietary names
 - Proprietary names (trade name(s)/trademark) (including the name of the country and the corresponding manufacturer)
 - Street names
- Chemical and physical properties
- Analytical methodologies and data used for identification and quantification
- Information on the frequency, quantities, and circumstances in which a new psychoactive substance is encountered, clearly identifying the source of information as follows:
 - Seizure

- Collected sample
- Biological sample
- Results of forensic analysis or other relevant analysis of substances.
 - The report should specify if other new psychoactive substances, controlled drugs, or other substances of interest have been identified in the seized and/or collected sample and/or biological sample
 - The type and amount of the substance and date of events
 - For seizures, the following should be specified:
 - Seizing authority
 - Geographical location of seizure
 - Place
 - City/town
 - If seizure was made at an airport, seaport, international mail centre, or other type of facility.
 - Date of seizure
 - Physical characteristics and quantity, including:
 - Physical form (powder, liquid, tablets, capsules, etc.)
 - Total quantity
 - Weight of individual item
 - Physical attributes, including:
 - Colour
 - Shape
 - Design, markings, logo
 - Number of tablets or capsules, etc.

- For dosage units specify the item weight (mg), diameter (mm), shape, logo/markings, etc.
- Concealment methods
- Container/packaging information
 - Description of how the substance(s) and/or products were packaged
 - Any retail product name or branding, if found on any packaging
 - Any mislabelling or misleading labelling
 - Any photographs, including packaging, shipping envelopes, logos, postal or express courier stamps, if available
- Countries of origin, transit, and destination
- Any other additional information from the investigation into the event
- For collected samples, the following should be specified:
 - Collecting authority
 - Geographical location
 - Place
 - City/town
 - Date of collection
 - Context of collection
 - If possible, include all information as described in seizures above
 - Any other additional information from the event
- For biological samples, the following should be specified:
 - Identifying authority
 - Reason for biological sample collection
 - Geographical location

- Place
- City/town
- Date of collection
- Type of biological matrix
- Whether the analysed material is from deceased persons (post-mortem) or from living individuals (ante-mortem)
- Results of forensic toxicology
- Case narrative
- Any other additional information from the investigation into the event

b) Use and patterns of use

This includes the available information on:

- Physical effects (positive and negative) as subjectively described by users and/or objectively observed
- Psychological effects (positive, negative) as subjectively described by users and/or objectively observed
- Behavioural effects
- Routes of administration
- Onset of action, duration, after-effects
- Dosage used
- Dosage units (tablets, capsules, etc.)
- Use in combination with other psychoactive substances (including controlled drugs and medicines)
- Users' knowledge about the substance and attractiveness to users
- Prevalence of use, including extent, frequency, age groups, gender

- Market or specific demand for the substance; name by which it is sold/bought, which may be its own name or that of a controlled substance in place of which it is offered (e.g. as a legal alternative)
- Price (in euro) at street level as indicated by users, or reported from seizures, or observed by professionals in health services, or from studies, or the published literature, etc.
- Perceived availability at consumer level

c) Manufacture or extraction

This includes the available information on:

- The chemical precursors and the means and methods that are known to have been used for manufacture of the substance, including:
 - Information on the precursors and if they are readily available or difficult to obtain (e.g. subject to restrictive measures at national level, expensive cost, etc.)
 - An explanation of the means and methods for manufacture, including whether the method of synthesis is easy or difficult (e.g. does it require sophisticated equipment or a high level of expertise)
- Means and methods that are known to have been used for the extraction of the substance
- Means and methods that are known to have been used for the processing/manufacturing of the substance into a product
- Information on the involvement of criminal groups in the manufacture or extraction of the substance

d) Distribution and distribution methods of the new psychoactive substance

This includes the available information on:

- The type of distribution and distribution methods used
- The size and scale of distribution operations
- The involvement of criminal groups in distribution operations

e) Trafficking of the new psychoactive substance

This includes the available information on:

- The type of trafficking (national or international)
- The size, scale, and methods of trafficking operations
- Information on the involvement of criminal groups in trafficking operations

f) Industrial, commercial, scientific, research, and medical use

This includes the available information on:

- Any known industrial, commercial, scientific, research, religious or ritual use
 - The extent of such use
 - The risks associated with such use
- Any known medical use, including:
 - If the new psychoactive substance is used as an active substance in a medicinal product for human or veterinary purposes
 - If the new psychoactive substance is used for synthesis (starting/intermediate material) of a medicinal product or an active substance of a medicinal product
 - If the new psychoactive substance is a metabolite of an active substance of a medicinal product, new psychoactive substance, controlled drug, or any other substance

g) Potential and identified risks

This includes the available information on:

- Pharmacology:
 - Pharmacodynamics
 - Psychological and behavioural effects
 - Safety pharmacology

- Pharmacokinetics
- Toxicology
- Serious adverse events:
 - Acute poisoning (the outcome should be reported as: non-fatal/fatal/unknown)
 - Death (the type of investigation should be reported: medico-legal death investigation/other)
 - Substance dependency/withdrawal
 - Birth defect/congenital anomaly
 - Other (the reporter must specify as precisely as possible the type of event)
 - Serious adverse events may or may not be subject to analytical confirmation through analysis of one or more biological samples and/or seizures and/or collected samples (see above for the main types of information that should be reported in such cases)
- Abuse liability and dependence producing potential:
 - Information from in vitro, animal, and human studies
 - Information from serious adverse events
 - Information from national pharmacovigilance and toxicovigilance systems
 - Information from drug treatment agencies
- Social risks:
 - Consequences from the manufacture, extraction, production, trafficking and distribution (including retail market), such as:
 - Violence, involvement of organised crime, public order and nuisance implications
 - Social consequences and social behaviour consequences, such as:
 - Crime, violence, disorderly conduct, drug-driving offences of users

- Information on whether or not the new psychoactive substance is already subject to restrictive measures at national level in a Member State:
 - Under drug control legislation
 - Under new psychoactive substance legislation
 - Under precursors control legislation
 - Under medicinal products legislation
 - Under any other type of legislation (such as licensing or registrations for trade, distribution, hazardous materials, chemicals, etc.)

10. Additional information

None.

11. Changes since last version

Not applicable.

12. References

1. Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (recast). [consolidated version]. <http://data.europa.eu/eli/reg/2006/1920/2018-11-23>
2. Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking. [Consolidated version]. http://data.europa.eu/eli/dec_framw/2004/757/2017-11-22