



European Monitoring Centre
for Drugs and Drug Addiction

GUIDANCE NOTE 4

Events of potential high impact on public health

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

Document ID: EU-EWS-OG-GN-4
Authors: Michael Evans-Brown
Version: 1.0
Effective date: 1 January 2020
Supersedes: Not applicable
Status: Public

1. Purpose

The purpose of this document is to provide examples of the types of events that may have the potential to have a high impact on public health as well as the rationale for their expedited reporting to the EMCDDA.

Certain types of events involving new psychoactive substances, controlled drugs, and other substances of interest on the drug market may pose a high public health impact. Expedited reporting of these types of events by the Member States is essential to support the early detection, assessment, and timely response to public health risks both at national- and EU-level. Such events may also reveal potential public health risks that had previously gone unrecognised (¹).

The Reitox national focal points should prioritise reporting any events that they judge to be events of potential high impact on public health (EPHIPH) to the EMCDDA. These should be reported using the relevant EMCDDA reporting tools with the relevant information clearly highlighted. Outbreaks should be reported using the outbreak reporting form found in Guidance Note 5.

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 Guidance Note applies to the EMCDDA and the Reitox national focal points.

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 the guidance in this document is adhered to.

¹ So-called 'accidents waiting to happen' where an event or situation may lead to a serious public health threat or potential near-misses that are a warning of a more serious event.

5. Documents needed for this Guidance Note:

- EMCDDA operating guidelines for the European Union Early Warning System on new psychoactive substances.
- Guidance Note 2: Formal notification of a new psychoactive substance
- Guidance Note 3: Information that should be reported by the Member States on a new psychoactive substance
- Guidance Note 5: Outbreaks
- Guidance Note 6: Intensive monitoring
- Guidance Note 7: Substances of high concern

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. Examples of events of potential high public health impact

Events that NFPs should prioritise reporting to the EMCDDA:

- Identification of a substance judged by the Member States to be a new psychoactive substance.
 - → See Guidance Note 1: Formal notification of a new psychoactive substance
- First identification in country of a new psychoactive substance.

- Cases of severe acute poisoning, severe chronic poisoning, and deaths subject to medico-legal investigation.
 - In particular, NFPs should prioritise the reporting of cases where the substance of interest is judged to have contributed to or caused the serious adverse event.
- Events involving new psychoactive substances under intensive monitoring → see Guidance Note 6: Intensive monitoring.
- Events that are unusual or unexpected for the given time and place.
- Outbreaks (including clusters) involving new psychoactive substances, controlled drugs, or any other substance of interest.
 - Suspected outbreaks should also be reported.
 - Also report outbreaks irrespective of whether the causative substance/agent has been confirmed or not.
 - Events that have a high risk of causing an outbreak.
 - → For more information, see Guidance Note 5: Outbreaks
- Events involving substances of high concern ⁽²⁾ → see Guidance Note 7: Substances of high concern.
- Events or situations that have a potential for cross-border (international) spread.
- Important health-related events at mass gathering events.
 - Examples include significant number of serious adverse events involving new psychoactive substances, controlled drugs, or any other substance of interest.
- Large seizures or other seizures of concern.
 - → including synthesis, production, packaging, distribution facilities.
- Mislabelling, substitution, and adulteration that could have a high public health impact.
Examples include:

⁽²⁾ Substance of high concern means any substance that is not a new psychoactive substance or controlled drug but that is toxic or otherwise hazardous and poses a high risk of acute or chronic poisoning or any other type of serious adverse event.

- → fake medicines containing fentanils.
- → fentanils in heroin.
- → atropine/scopolamine in cocaine.
- → PMMA sold as ecstasy tablets.
- Detection of high strength/dose products.
- Infectious diseases and biological contamination of substances.
 - → especially events involving outbreaks (including clusters).
- Events involving crime groups.
 - → especially events involving organised crime.

Other events that should also be reported in a timely manner

- New products and technologies, as well as new ways of using substances. Examples include:
 - → nasal sprays.
 - → vaping.
- New diluents, adulterants, impurities, or contaminants.
- New marketing techniques.
- New user groups.

9. Additional information

None.

10. Changes since the last version

Not applicable.

11. 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