European Monitoring Centre
for Drugs and Drug Addiction

GUIDANCE NOTE 5
Outbreaks

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 the rationale, process, roles, and responsibilities for reporting an outbreak of poisonings, infections, or any other type of serious adverse event within the European Union associated with new psychoactive substances or any other substances of interest. This is in order to ensure a systematic, uniform, reproducible, and, transparent approach is used throughout.

The term *outbreak* means a localised increase in the number of cases of serious adverse events (poisoning, injury, or disease) in excess of what would normally be expected in a given area or among a specific group of people over a particular period of time. An outbreak may occur in a restricted geographical area, or extend over several countries.

For the purposes of this document, a 'cluster' is to be regarded as a synonym for outbreak. Both suspected and confirmed outbreaks should be reported to the EMCDDA. You should also report outbreaks even if the causative substance/agent has not been established/identified.

Reitox national focal points should use their judgement in determining when an outbreak has occurred and when to report it to the EMCDDA. *Typically, an outbreak should be considered when three or more cases present.* An outbreak ends when the number of new reported serious adverse events drops back to the number normally expected.

Outbreaks are classed as events of potential high public health impact and qualify for expedited reporting to the EMCDDA.

See: Guidance Note 4: Events of a potential high impact on public health

This document also provides a reporting form (*outbreak reporting form*) that allows the structured reporting of essential information related to an outbreak. This will allow the EMCDDA to analyse and assess any threats posed by the outbreak for the purposes of early warning, including the detection of cross-border threats. Following a declaration that an outbreak is over, the information will also be used examine possible options to strengthen future preparedness planning and responses measures as part of the EMCDDA's early warning activities.

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

!! Remember: If in doubt, report it.

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 process in this Guidance Note is adhered to.

5. Documents needed for this Guidance Note:

- EMCDDA operating guidelines for the European Union Early Warning System on new psychoactive substances
- Guidance Note 2: Information that should be reported by the Member States on a new psychoactive substance
- Guidance Note 3: Events of potential high impact on public health
- Guidance Note 5: Intensive monitoring
- Guidance Note 6: 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. 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

ORF: Outbreak reporting form

9. Process steps

- Start of process.
    - Outbreak detected.
        - NFP detects outbreak.
            - NFP reports outbreak to EMCDDA using ORF.
            - EMCDDA acknowledges receipt of the ORF from NFP.
        - EMCDDA detects outbreak.
            - EMCDDA seeks verification of outbreak from NFP.
                - NFP refutes outbreak → end of process.
                - NFP confirms outbreak → process continues.
                - NFP reports outbreak to EMCDDA using ORF.
                - EMCDDA acknowledges receipt of the ORF from NFP.
        - EMCDDA reviews, analyses, and assesses the information reported in ORF.
            - If clarifications are required:
                - EMCDDA requests clarifications from NFP.

- NFP provides clarifications to the EMCDDA.

- EMCDDA assigns one or more (internal) recommendations for action
  → See: Recommendation for action, Guidance Note 1.

- NFP should provide updates on the event using ORF when significant new information is available.

- Once the outbreak is declared over, the NFP should send a final report to the EMCDDA using the ORF.

- End of process

10. Outbreak Reporting Form (ORF)

→ If in doubt, report it.

→ Return this completed form by email to: ews@emcdda.europa.eu

- Title of report ([1])

  - Keep the title short and memorable. Include information on the:

    - number of people affected

    - type of event or threat

    - substance(s) of interest or other hazard

    - geographical location

([1]) Examples of titles:

[OUTBREAK] 6 deaths linked to fake oxycodone tablets containing methoxyacetylfentanyl — Atlanta, Georgia, United States, June 2018

[OUTBREAK] Outbreak of severe bleeding linked to use of synthetic cannabinoid products — Chicago, Illinois, United States, March 2018

[OUTBREAK] Outbreak of Salmonella infections linked to kratom products — Multiple States, United States, 2017–2018

Use the email subject line of [OUTBREAK] {NUMBER OF PEOPLE AFFECTED} {TYPE OF EVENT/THREAT}, {SUBSTANCE(S) OF INTEREST OR OTHER HAZARD} — {CITY}, {REGION}, {COUNTRY}, {MM YYYY}

        - date

- Reporting country
- Reporting agency
- Date of report
- Name of reporter
- First Report/Update Report [ordinal number]/Final Report [Delete as appropriate]
- Summary of event
    - What happened?
    - Who was affected and how many were affected?
    - Where and when did the outbreak take place?
    - Why / how did it occur?
- Is there a risk that the threat could spread to other countries? ([2])
    - Yes → write in why there is a risk
    - No
- Is the event unusual or unexpected?
    - Yes → write in why it is unusual or unexpected
    - No
- Date of first case
- Geographical location
    - Country
    - City/town

([2]) Has a cross border threat detected? Review the relevance of the threat under Decision No 1082/2013/EU. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013D1082

- Name of the substance(s)/product(s) involved
    - Indicate if this is suspected or analytically confirmed.
    - Please attach pictures if available.
- Does the event involve adulteration/contamination of a substance/product ?
    - Yes → write in the adulterant/contaminant
    - No
- Is the substance/product still available on the market?
    - Yes
    - No
    - Unknown
- Number of people affected (indicate if this is an estimate):
    - Did the event involve:
        - Poisonings
            - Yes → how many people have been poisoned?
                - What is the severity of the poisoning and how many cases have you had for each?
                    - Unclassified (U)
                    - None (0)
                    - Minor (1)
                    - Moderate (2)
                    - Severe (3)
                    - Fatal (4)
            - No
        - Deaths (medico-legal investigations)

- Yes → how many people have died?
- No

- Other → write in the type of serious adverse event and how many people were affected
- Have any cases been analytically confirmed?
  - Yes/No
  - How were these cases confirmed?
    - Biological samples taken from patients → write in the results
    - Drug sample related to the event → write in the results
    - Other… → write in

- Physical/dosage form (e.g. tablet, powder, herbal smoking mixture, nasal spray)
- Route of administration
- What symptoms and clinical features have been reported?
- What treatment has been provided?
  - Were antidotes used to treat the patients?
    - Yes → write in the name of the antidote
      - Did the antidote work?
      - Do local healthcare facilities have appropriate antidotes and adequate supply?
    - No
- Is the event ongoing?
  - Yes
  - No
  - Other… → write in

- Source traceback investigation
    - Comments
    - Has an investigation been initiated to determine the source of the substance of interest?
- What action has been taken to deal with the event by…
    - Health agencies → write in
    - Law enforcement → write in
    - Other… → write in
    - Please include details of any other response measures.
- Has an alert or other type of risk communication been issued?
    - Yes → please write in to whom this has been issued and provide copies or links of the communications
    - No
- Is any advice or technical support required from the EMCDDA?
    - Yes → write in what support you need
    - No
- Additional information

11. Additional information

None.

12. Changes since last version

Not applicable.