GUIDANCE NOTE 7
Substances of high concern
EMCDDA operating guidelines for the European Union Early Warning System on new psychoactive substances
1. Purpose

The purpose of this document is to provide a list of substances of high concern monitored by the EMCDDA and the rationale for reporting events involving the identification of such substances. This is in order to ensure a systematic, uniform, reproducible, and transparent approach is used throughout.

What is a substance of high concern?

A substance of high concern is 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. Typically, such substances are capable of causing outbreaks of mass poisonings and thus identifications linked to the NPS market or controlled drug market are classed as events of potential high impact on public health.

The identification of a substance of high concern is subject to expedited reporting by the Reitox National Focal Points when:

- It is identified with or sold as a new psychoactive substance; or,
- it is identified with or sold as controlled drug; or
- there is reasonable probability that it is linked in some way to the NPS market or the controlled drug market.
- It is identified in biological sample taken from a serious adverse event and there is reasonable probability that exposure to the substance of high concern was linked in some way to the NPS market or controlled drug market. Note where it is known that the substance has been used therapeutically in the course of medical treatment (e.g. atropine), the identification is excluded from reporting.

→ If in doubt, report it. You can contact us at: ews@emcdda.europa.eu

The Reitox National Focal Points should submit reports involving substances of high concern using the relevant EMCDDA reporting tools and clearly highlight the relevant information.

Substances are added to the list by the EMCDDA based on reports of identifications involving serious adverse events reported either by the Member States or from any other information at the disposal of the EMCDDA (such as the scientific and medical literature).

Member States should report any additional substances that they judge to be a substance of high concern along with a brief rationale to the EMCDDA for consideration for inclusion on the list.
Guidance Note: Early Warning System Operating Guidelines

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 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: Types of 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 4: Outbreaks

6. Related documents


7. Terminology and definitions

- Guidance Note 1: Terminology and definitions

8. List of substances of high concern

List current as of 1 January 2020

- Atropine
- Brodifacoum
- Bromadiolone
- Clenbuterol
- Difenacoum
- Glibenclamide
- Glyburide
- Haloperidol
- Lead
- Scopolamine
- Strychnine
- Vitamin E acetate (when intended for inhalation/smoking, such as in an e-liquid or other dosage form)

9. Additional information

Below are some references related identifications of substances of high concern involving serious adverse events related to the NPS market and drug market.
Atropine


Brodifacoum


Bromadiolone


Clenbuterol


Difenacoum


Glyburide


Haloperidol


Fake diazepam tablets that did not contain diazepam but contained haloperidol (anti-psychotic) caused an outbreak of mass poisoning involving 930 cases of dystonia (muscles contract involuntarily, causing repetitive or twisting movements) — Ituri, Democratic Republic of Congo, 2014–2015. Analytical confirmation from 9 urine samples from patients. Tablets in circulation were analysed and found to contain 10–20 mg of haloperidol per tablet. Tablets were imprinted with the letters ‘AGOG’ and containers were labelled as diazepam.

See also:


Mis-selling of haloperidol as Klonopin (clonazepam) or Valium (diazepam) caused an outbreak involving 7 cases of dystonia — Illinois, United States, No date. No analytical confirmation. Visual confirmation from 1 tablet (MYLAN 327; haloperidol 5 mg) provided by a patient.

Lead


Scopolamine


Strychnine


Vitamin E acetate


10. Changes since last version

Not applicable.