EU EARLY WARNING SYSTEM SITUATION REPORT

Situation report 1 — June 2020

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1. Purpose

The purpose of this situation report is to: provide a summary of recent information reported to the EU Early Warning System, including formal notifications and other important signals; highlight important operational issues; and, provide other resources identified by the EMCDDA. This report may contain information that might be under verification.

The information and resources in this report are intended to strengthen situational awareness within the Network, as well as to help the Network to prepare for, respond to, and recover from public health and social threats caused by new psychoactive substances (NPS) and other substances of interest.

A specific focus of this report is to:

- highlight recent resources that examine the potential impact of the COVID-19 pandemic on the drug markets and risks to people who use drugs; and,
- request that the Network expedite reporting of any event, especially those related to the pandemic, that you consider may have a potential high impact on public health.

Please send us your feedback

The EMCDDA welcomes your feedback on the situation report, including improvements and ideas for future editions.

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

2. General update of the NPS situation

2.1 Notifications

As of 16 June 2020, a total of 14 new psychoactive substances have been formally notified by the Member States so far this year. These comprise:

- Arylalkylamines: 2 (BOH-PHP, BOH-2C-B)
- Arylcyclohexylamines: 1 (methoxpropamine)
- Cathinones: 3 (α-PCYP, 3F-α-PHP, 4F-3-methyl-α-PVP)
• Opioids: 2 (etazene, brorphine)
• Others: 3 (citicoline, nefiracetam, clozapine)
• Synthetic cannabinoids: 2 (BENZYL-4CN-BINACA, CUMYL-CBMINACA)
• Tryptamines: 1 (N-methyltryptamine)

Section 7 provides further details of the notified substances, including links to their EDND profiles and formal notifications.

**Note: Formal notification of new psychoactive substances**

Reitox national focal points should expedite reporting to the EMCDDA of any substance that they judge to be a new psychoactive substance. The EMCDDA will then assess the substance in order to determine if a formal notification should be issued.

The formal notification of a new psychoactive substance ensures that members of the Network are alerted as soon as possible following the identification of a new psychoactive substance on the drug market in Europe. This allows the network to detect and assess any potential threats, as well as to identify and implement any response measures that might be required. Importantly, the information provided in the formal notification allows forensic science and toxicology laboratories to include the substance in their analytical screening allowing it to be identified and therefore monitored.

➔ Further details, including information on the process that should be followed, can be found in **EWS guidance note 2: Formal notification of a new psychoactive substance**.

**Note: First identification in country of a new psychoactive substance**

Reitox national focal points should expedite reporting to the EMCDDA the first time a new psychoactive substance is identified in their country. Known as a *first identification in country* (FIC), the timely reporting of FICs help the EMCDDA understand the availability and diffusion of a new psychoactive substance in Europe. Reitox national focal points should liaise regularly with the forensic science and toxicology laboratories in their national early warning system in order to determine in a timely manner when an NPS is identified for the first time in their country.

➔ A list of notified new psychoactive substances is available on request from the EMCDDA.
2.2 Notification in focus: Etazene

Etazene was notified as a new psychoactive substance on 1 June 2020 by Poland (EU-EWS-RCS-FN-2020-0012). The substance belongs to the 2-benzylbenzimidazole group of synthetic opioid analgesics, many of which have levels of analgesic potency several orders of magnitude higher than that of morphine [1]. In an animal model of analgesia, etazene was assessed to be 70 times as potent as morphine [2].

The notification of etazene was based on its identification in a seizure of 0.078 grams of grey powder made by Polish police on 30 March 2020 that was en-route to Germany. The circumstances of the case are reported as small scale international trafficking. Finland has also reported a seizure of liquid (as nasal sprays) made by customs on 2 March 2020.

The 2-benzylbenzimidazole group of opioids includes etonitazene and clonitazene, which are under international control, and isotonitazene [1], which first emerged on the NPS market in Europe in 2019, and was recently the subject of an EMCDDA initial report (Section 2.5) and a risk assessment due to the public health and social risks it may pose at Union level (Section 2.6). After isotonitazene, etazene is the second substance from the 2-benzylbenzimidazole group of opioids to be identified on the European drug market since 2019. The recent emergence of this group of opioids, and others, such as piperidylthiambutene, AP-237, 2-Me-AP-237, and 2F-viminol, may reflect a switch away from the fentanils following generic control measures that were introduced in China and the United States in 2019 [3].

Since 2009, a total of 59 new opioids, such as etazene, have been identified on the drug market in Europe; this includes 43 (73%) that were reported for the first time between January 2016 and June 2020. While currently playing a small role in the overall market, new opioids are of special concern to public health because they can pose a high risk of life-threatening poisoning from respiratory depression.

The EMCDDA requests that the Network report to the EMCDDA any identifications of etazene, especially first identifications in country (FICs), in a timely manner in order to help us understand the risks this substance may pose to Europe.

➔ Further information on etazene

2.3 Signals

Increase in identification of MDMB-4en-PINACA — Europe, 2019–2020 (ongoing)

MDMB-4en-PINACA is a synthetic cannabinoid that was first identified in Europe in 2017. Since 2019, there has been an increase in the number of identifications of the substance reported to the
EMCDDA. So far, MDMB-4en-PINACA has been identified in 17 countries in the Network: Austria, Belgium, Bulgaria, Cyprus, France, Germany, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, Turkey, and the United Kingdom. Of these countries, 12 (70%) reported the identification of the substance for the first time in 2019.

Approximately 160 seizures have been reported by 15 countries so far. The large majority of the seizures reported (143 cases (89%)) occurred in 2019. The most recent seizure reported to the EMCDDA occurred in February 2020. The EMCDDA is currently preparing an advisory on MDMB-4en-PINACA which will be issued shortly. In the meantime, the EMCDDA requests that the Network report any events involving MDMB-4en-PINACA that have the potential to have high impact on public health.

➔ Further information on MDMB-4en-PINACA

**Note: MDMB-4en-PINACA and events of potential high impact on public health**

The EMCDDA requests that the Network report any events involving MDMB-4en-PINACA that have the potential to have high impact on public health. These types of events include:

- First identifications in country (FICs)
- Cases of severe acute poisoning, severe chronic poisoning, and deaths subject to medico-legal investigation
- Events that are unusual or unexpected for a given time or place
- Outbreaks
- Events or situations that have the potential for cross-border (international spread)
- Large seizures or other seizures of concern
- Mislabelling, substitution, and adulteration
- Detection of high strength/dose products
- Events involving crime groups

➔ Further guidance on such types of events are provided in EWS guidance note 4: Events of potential high impact on public health.
2.4 Intensive monitoring

*Isotonitazene*

On 7 February 2020, the EMCDDA placed the synthetic opioid isotonitazene on the intensive monitoring list due to the potential public health risks that it may pose (EU-EWS-RCS-AD-2020-0001). Since then, other response actions include an initial report (Section 2.5) and risk assessment (Section 2.6).

**Note: Isotonitazene and intensive monitoring**

Due to the potential public health risk posed by isotonitazene, the Network should continue to expedite reporting of any event involving the substance to the EMCDDA until further notice.

→ See EWS guidance note 6: Intensive monitoring for more information on intensive monitoring.

2.5 Initial reports

*Isotonitazene*

Based on the information reported to the Early Warning System, and, in accordance with Article 5a of the Regulation, on 20 February 2020, the EMCDDA assessed the existing information on isotonitazene. The EMCDDA concluded that the assessment gave rise to concerns that isotonitazene may pose health or social risks at Union level, and, consequently, determined that an initial report should be produced in accordance with Article 5b of the Regulation. The initial report was submitted to the Commission and Member States on 3 April 2020. Based on the findings of the initial report, on 17 April 2020, the Commission requested that the EMCDDA carry out a risk assessment on isotonitazene in accordance with Article 5c of the Regulation (Section 2.6).

→ Download the EMCDDA initial report on isotonitazene

2.6 Risk assessments

*Isotonitazene*

In accordance with Article 5c of Regulation (EC) 1920/2006, and based on a request from the Commission, on 26 May 2020, the Scientific Committee of the EMCDDA assessed the health and social risks posed by the synthetic opioid isotonitazene. The risk assessment report drawn-up by
the Committee was submitted to the Commission and Member States on Friday 29 May 2020. Based on the report, the Commission will now decide on the need for control measures in accordance with Article 1a of Council Framework Decision 2004/757/JHA.

In order to support the risk assessment, the EMCDDA produced a technical report on isotonitazene that examined what is known, and what is not known, about the epidemiology, pharmacology, toxicology, public health risks, and social risks of this potent opioid.

→ Download the EMCDDA technical report on isotonitazene

3. Operational matters

3.1 Decline in reporting serious adverse events

Over the last 18 months, the EMCDDA has noticed a decline in the number of serious adverse events being reported through event-based reporting (i.e. as individual case reports). While the reasons for this decline are currently unclear, the EMCDDA encourages the Reitox national focal points to report serious adverse events in a timely manner. We also encourage you to contact us if you have any issues regarding reporting serious adverse events. In particular the NFPs are reminded that:

- All cases of severe acute poisoning, severe chronic poisoning, and deaths subject to medico-legal investigation are classed as events of potential high impact on public health, and therefore subject to expedited reporting to the EMCDDA.

- Reporting of cases where the substance of interest is judged to have contributed to or caused the serious adverse event should be prioritised.

**Note: How to report serious adverse events**

NFPs are reminded that, until further notice, serious adverse events should continue to be reported using the Serious Adverse Event Reporting Form (SAERF), rather than through the EDND.

→ Download the Serious Adverse Event Reporting Form (SAERF)

→ If you have any questions, please contact us at: ews@emcdda.europa.eu
3.2 Operational guidance

On 1 January 2020, the new EMCDDA operating guidelines for the European Union Early Warning System on new psychoactive substances came into effect. The guidelines provide the rationale, steps, procedures, roles, and responsibilities for the operation of the EU Early Warning System (EWS). They reflect the requirements of Regulation (EC) No 1920/2006 (as amended) and Council Framework Decision 2004/757/JHA (as amended) with respect to information exchange and the early warning system, as well as for the initial report, risk assessment, and control measures. The guidelines are accompanied by EWS guidance notes, see the full list below.

- EMCDDA operating guidelines for the European Union Early Warning System on new psychoactive substances
- EWS guidance note 1: Terminology and definitions
- EWS guidance note 2: Formal notification of a new psychoactive substance
- EWS guidance note 3: Information that should be reported by the Member States on a new psychoactive substance
- EWS guidance note 4: Events of potential high impact on public health
- EWS guidance note 5: Outbreaks
- EWS guidance note 6: Intensive monitoring
- EWS guidance note 7: Substances of high concern

4. Subject focus: Potential impact of the COVID-19 pandemic on the drug markets and risks to people who use drugs

On 22 April 2020, the EMCDDA issued an alert to the Network highlighting, that, since January 2020, the coronavirus disease (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has led to major disruptions in trade and travel across the world (EU-EWS-RCS-AL-2020-0001). As the supply chains for drugs are globalised and many countries have implemented physical distancing measures (including stay-at-home restrictions for entire regions or countries) in order to reduce further the transmission of the virus, it is possible that the pandemic could have a major impact on the drug markets, including on the availability of controlled drugs and new psychoactive substances, as well as the materials and equipment used to make them.
The alert also highlighted that although there is currently limited scientific evidence, based on previous experiences with disruptions to the drug markets, the impact of the pandemic could lead to localised or more broader changes in use and patterns of use, as well as an increased risk of substitution, misselling, adulteration, contamination, and dilution with a range of potentially dangerous and sometimes highly toxic substances; in some cases this could cause outbreaks. These may be single ‘one off’ events, or short-lived or longer lasting changes. Laboratory (analytically) confirmed reports from forensic science and toxicology laboratories will continue to play a central role in the early detection and response to such events and changes.

The initial impact of the pandemic on the European drug market has now been analysed by the EMCDDA and Europol [4,5]. The UNODC has produced an analysis at international level [6] as well as guidelines for the safe handling of substances and management of exposure risk for law enforcement and customs officers [7,8]. In addition, some countries, such as France [9,10] and Canada [11], have also produced analyses of changes to the drug markets and the risks to people who use drugs. Some information is also available from the Global Drug Survey that has examined some of the impacts of the pandemic on use and patterns of use in people who use drugs [12].

The key findings related to the European drug market [4] are:

- Global restrictions on travel and other measures as a result of the COVID-19 pandemic have had a temporary disruptive impact on the drug market leading to shortages of and higher prices for some drugs, but the situation is subject to rapid change.

- The disruption to the supply chain and logistics of drug trafficking in Europe is most evident at the distribution level, because of social distancing measures.

- The movement of bulk quantities of drugs between EU Member States has continued despite the introduction of border controls due to the continued commercial transportation of goods throughout the EU.

- In relation to cocaine, in particular, there is little evidence of disruption to activity at the wholesale importation level; however, experts in some countries report increasing prices and decreasing purity at the consumer level, indicative of localised supply shortages.

- Organised crime groups (OCGs) remain resilient and are adapting their modi operandi to the current situation, further exploiting secure communication channels and adapting transportation models, trafficking routes and concealment methods.

- The current instability has led to an increasingly volatile environment for criminal businesses along the supply chain in Europe and appears to have resulted in increased levels of violence among mid-level suppliers and distributors.
• Surface web and darknet markets, social media and secure encrypted communication applications now appear to be playing a more prominent role in the sourcing of drugs at user level. Home deliveries, less face-to-face dealing and less reliance on cash as a form of payment seem to be increasing for individual transactions and it is possible that behavioural changes, once established, will persist over the longer term.

• Shortages of cannabis resin and possible stockpiling of herbal cannabis by users have led to inflated retail prices for both cannabis resin and herbal cannabis in some Member States. The domestic production of herbal cannabis appears not to have been significantly disrupted.

• Heroin trafficking seems to be continuing on many of the known routes. The availability of heroin has decreased in some areas but this varies depending on national confinement rules and restrictions on movement, with higher prices also reported in some places. Community-based information from drug workers also suggests that there have been some shortages and also the possibility that heroin has been substituted with other substances. These substances may include synthetic opioids (diverted medicines or new psychoactive substances (NPS)) or alternative drugs (e.g. crack cocaine, amphetamine, synthetic cathinones), and it is possible that some of these substances may feature more prominently in the drug market in the longer term in affected places.

• Cocaine trafficking using maritime shipping containers has continued at levels that are comparable to or even possibly higher than those seen in 2019. European and Colombian data show that significant seizures were made in the first part of 2020, despite the restrictions resulting from the COVID-19 pandemic. Unsurprisingly, trafficking by air passengers has decreased dramatically.

• Synthetic drug production continues in the main European producing zone in the Netherlands and Belgium, as evidenced by the number of illicit laboratories dismantled and dumpsites reported. However, in Europe and globally, the demand for synthetic drugs used in recreational settings, in particular MDMA, seems to have diminished in the short term due to the closure of venues and cancellation of festivals. The wholesale prices of amphetamine and MDMA have increased in several countries; however, the Netherlands reports decreasing prices, indicative of attempts to increase sales.

• Due to limited data, it is not possible to assess how the NPS market has been impacted during the COVID-19 pandemic.

The EMCDDA continues to highlight that, where possible, there may be a need for a high level of vigilance in order to ensure early detection, reporting, assessment, and responses to changes to the drug markets related to the pandemic that may have a high impact on public health.

In addition we also request that:
• Until further notice, you expedite reporting to the EMCDDA of any event, especially those related to the pandemic, that you consider may have a potential high impact on public health. Examples of the types of events that should be reported are listed in EWS guidance note 4: Events of potential high impact on public health.

• You report to the EMCDDA any general information you have on changes to the drug markets and risks to users related to the pandemic.

→ A full list of the EMCDDA's COVID-19 resources are available on our website

5. Update from the national early-warning systems

If you have any information that you would like to share with the Network for the next edition of the situation report, please email us at: ews@emcdda.europa.eu

Items you may wish to send us includes: developments at national level (NPS situation, policy, legislative, and regulatory developments, EWS developments), reports and scientific literature, and meetings and events.

6. Publications and resources of interest

Pharmacology and toxicology


Epidemiology

NL: https://www.trimbos.nl/docs/dd7ce48d-64e9-4994-9f65-8bbea36b0d3b.pdf


Hanke K, et al. Outbreak of 27 cases of HIV infections associated with synthetic cathinone use — Munich, Germany, 2015–2018. (First case diagnosed in 2015; last in 2018. In 8/18 (44%) cases α-PVT and/or PV8 were identified from dried serum spots.) Open Forum Infect Dis. 2020. https://doi.org/10.1093/ofid/ofaa192


Legislation and policy


Meeting abstracts


7. New psychoactive substances notified in 2020 — provisional list, 1 January–16 June 2020


8. **Clozapine** (3-chloro-6-(4-methylpiperazin-1-yl)-11\(H\)-benzo[b][1,4]benzodiazepine) — other, police seizure, United Kingdom, 23 December 2016. Notified: 15 April 2020. EU-EWS-RCS-FN-2020-0008


11. **CUMYL-CBMINACA** (1-(cyclobutylmethyl)-N-(2-phenylpropan-2-yl)-1\(H\)-indazole-3-carboxamide) — synthetic cannabinoid, collected sample (University Medical Center Freiburg), Germany, 17 February 2020. Notified: 6 May 2020. EU-EWS-RCS-FN-2020-0011

12. **Etazene** (2-[(4-ethoxyphenyl)methyl]-N,N-diethyl-1\(H\)-benzimidazole-1-ethanamine) — opioid, police seizure, Poland, 31 March 2020 (also seized by Finnish customs on 2 March 2020). Notified: 1 June 2020. EU-EWS-RCS-FN-2020-0012

13. **Brorphine** (1-[1-[1-(4-bromophenyl)ethyl]-4-piperidinyl]-1,3-dihydro-2\(H\)-benzimidazol-2-one) — opioid, police seizure (collected by Swedish Post and Telecom Authority), Sweden, 25 March 2020. Notified: 4 June 2020. EU-EWS-RCS-FN-2020-0013

8. References


