SO-PREP

An assessment of national synthetic opioid preparedness in five countries: Belgium, Estonia, Finland, Germany, and the Netherlands

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○ Representative of the Belgian Federal Police- Section Serious and Organized Crime

Estonia ○ Estonian Forensic Science Institute
○ Estonian Police and Border Guard Board, Northern Prefecture ○ State Agency of Medicines

- Viljandi Hospital
- Tallinn Emergency Medical Services ○ NGO Convictus Estonia NGO Estonian Association of People Who Use Psychotropic Substances (LUNEST)

Finland ○ Finnish Institute for Health and Welfare, THL ○ Drug Information Focal Point (Reitox), THL ○ The Finnish Medicines Agency Fimea ○ The Ministry of Social Affairs and Health ○ A-Clinic Foundation

- National Board of Customs of Finland ○ National Bureau of Investigation
- The National Police Board of Finland

Germany ○ Institut für Therapieforschung München/German Monitoring Center for Drugs and Drug Addiction (the Reitox focal point in Germany) ○ Condrobs München

- Legal High Ingredients (Legal High Inhaltsstoffe)
- Institute of Addiction Research; Frankfurt University of Applied Sciences

The Netherlands ○ Trimbos Institute, the Netherlands Focal Point

- Trimbos Institute, Drugs Information and Monitoring System (DIMS), ○ The Institute for the Safe Use of Medicines' and the Taskforce Opioids ○ The Ministry of Justice and Security ○ The research project TAPTOE
- Foundation Mainline, harm reduction agency with outreach activities
- The National Institute for Public Health and Environment

Abbreviations

EMCCDA	European Monitoring Center for Drugs and Drug Addiction
EWS	Early Warning System
NGO	Nongovernmental organizations
NPS	New psychoactive substances
PWID	People who inject drugs
PWUD	People who use drugs
SO	Synthetic Opioids
THN	Take-Home Naloxone

1. Introduction

The rapid emergence of synthetic drugs constitutes one of the most significant drug-related health threats worldwide. Along with synthetic drugs, the emergence of NPS has become a significant challenge to drug policy and drug control strategies. By the end of 2020, a total of 830 NPS were being monitored by the EMCDDA, of which 67 were SOs, including ten reported for the first time in 2020 (EMCDDA, 2021). While SOs are not the largest group of NPS, they are associated with the highest risk of overdose of all NPS. The use of SOs and the number of drug-related deaths have been increasing in many European countries.

According to the countries participating in this report, the use of illicit SOs has been relatively stable during the last years, except in Estonia. At the beginning of the 2000s, the country was hit by several waves of fentanyl overdoses. However, the most recent data shows an increase in SO prevalence and incidence in several countries across Europe.

Many European countries have also witnessed a steady increase in prescription opioids over the past ten years, causing increasing attention and concern about the use of prescription opioids.

In Europe, highly potent synthetic opioids (SO) and related overdoses are a growing threat to public health and safety. SO-PREP is a two-year European project focusing on strengthening health systems' preparedness to timely and effectively monitor and respond to increases in the prevalence, use, and harms of SO.

This report describes the situation in five European countries regarding the use of SO and the available preparedness methods for dealing with potential increases in SO use and incidents. The purpose of the report is to identify good practices as well as gaps in national and local synthetic-opioid preparedness strategies. The added value of conducting this in-depth analysis in five countries, with very different SO situations and health care systems, is that it can help European countries learn from one another. Ultimately, the information presented in this report can help strengthen response capacities and SO preparedness.

The aim of the report was to assess national and local detection and preparedness models and strategies for a potential SO crisis. Key experts discussed SO preparedness strategies in

- monitoring systems,
- health systems,
- the law enforcement systems, and
- early warning systems.

They also discussed how their countries may need to scale up to be better prepared for increases in the use and harms of SO.

2. Methodology

The report is based on expert group meetings and individual interviews in the five SO-PREP projectparticipating countries (Figure 1). The five countries are Belgium, Estonia, Finland, Germany, and the Netherlands.

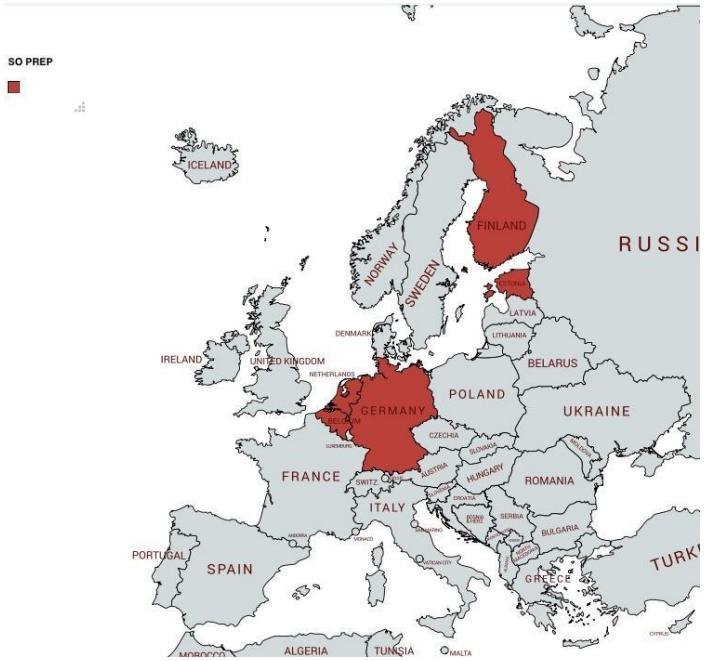

Figure 1: SO-PREP project partners

Each country prepared a country report on its national SO preparedness. The national reports provide rich, in-depth information about existing practices of national SO-preparedness, as well as needs and challenges. The present report summarizes the key findings from the five-country reports, which can be found in the Annex.

The Finnish Institute for Health and Welfare developed questions and guidelines to be used in the expert meetings, and also provided the structure of the country reports. All SO-PREP project partners collected indepth data and information on existing practices of the national SO-preparedness in their country. Data was collected through online group meetings and/or individual interviews with experts from the fields listed below. The interviews took place between November 2020 and February 2021.

The expert groups or individual interviews included participants from:

- ✓ Forensic institutes/relevant laboratories
- ✓ EMCDDA national Focal Points
- ✓ Representatives of the ministries
- ✓ Law enforcement sector: Police, Customs, and Border Forces
- ✓ Health care services: Ambulance / Emergency care units
- ✓ Poison center
- ✓ National Medicines Agency
- ✓ Local commissioners and providers of services for people who use drugs ✓ NGOs, Low-threshold services

3. Key findings of the five country reports

3.1 Monitoring systems

With the rapidly changing drug markets and a growing number of new SO, investing in enhanced SO monitoring systems is crucial, particularly against the backdrop of the drug overdose crises experienced by the United States and Canada.

There are many different monitoring and data collection tools and indicators, including surveys, drug checking services, scientific research, treatment indicators, and supply indicators for detecting the use of synthetic opioids. This chapter examines the challenges and shortcomings of monitoring the prevalence and use of synthetic opioids and explores how these challenges could be addressed. ***Challenges in the monitoring systems and how to address them***

- One of the challenges is that drug monitoring services and tools often do not specifically focus on SO in their data collection and/or analysis due to their low prevalence. For example, surveys do not always have "synthetic opioids" as a distinct category, and small doses may be difficult to detect in wastewater analysis (Cannaert et al., 2018). Therefore, the true extent of the (nonmedical) use of illicit synthetic opioids is likely underestimated.
- There are technical differences between countries regarding data coverage and detail; deaths due to illicit drugs are likely underreported.
- Lack of anonymous drug-checking possibilities in Finland, Estonia, and Germany.
- Long waiting times for forensic expertise.
- There is a need to stay up-to-date on the newest trends involving social media and the dark web, including closely monitoring the way drugs are distributed while also using these technologies as a tool for harm reduction.
- There is also a need for better and more detailed monitoring of the availability and use of SO in different populations, including people with problematic drug use, as well as the general population.
- There is limited insight into the size, background, and motives of persons using SO.
- Every country should invest in scientific research on NPS and online drug markets, and if possible, consider including “synthetic opioids” as a distinct category in surveys.
- There should be more exchange of information between the drug service centers and the police in order to protect the health and safety of the PWUD.
- Wastewater analysis (the Netherlands, Finland, Belgium, and Estonia) provides information on the presence of drugs in the area of a wastewater network almost in real-time. Wastewater analysis is a good indicator for detecting the use of certain drugs; however, this method also has many challenges and things to consider when interpreting the data. For example, it is impossible to distinguish between legal and illegal use of opioids in wastewater analysis.

Examples of good practices

- **Drugs Information and Monitoring System (DIMS)[1]**

[1] See the annexed country report for more details.

In the Netherlands, the monitoring system is a well-developed, elaborate, and comprehensive system to monitor use and incidents with illegal drugs with input from various sources, such as law enforcement

agencies, the health care system, and consumers. In particular, the consumer input—provided by user panels like in the 'Antenne' research in Amsterdam and the nationwide Drug Information and Monitoring System (DIMS)—is a special asset for monitoring and understanding trends and patterns of drug availability and use. DIMS is funded by the Ministry of Health and local treatment agencies, coordinated by the Trimbos Institute. It is one of the oldest drug-testing systems worldwide. In 2018, 13,540 visitors supplied 12,634 samples for testing. The staff of DIMS also monitors the online markets (in both the clearnet and the darknet) on the sale of substances and other consumer trends. One weakness of the drug checking service is that it is not fully known what groups use these services. In general, it seems that it is mostly recreational users that make use of the services, while marginalized drug users do not.

- ✓ **Monthly reports**

The NGO Estonian Association of People Who Use Psychotropic Substances (LUNEST) has been making a monthly report to NIHD on the situation in the drug market and matters related to services. This report is also shared with the police. Information for this report is gathered all over Estonia – from PWUD, services (including mobile harm reduction units), partners, NGOs.[2]

3.2 Health systems

A health system (or health care system) plays a fundamental role in preparing communities to respond to and recover from health threats and emergencies. The health care system refers to the institutions, people, and resources involved in delivering health care to individuals (WHO, 2021; WHO, 2007).

The WHO recommends that naloxone—an opioid antagonist—should be available to any person likely to witness an overdose. However, in SO-PREP project countries, take-home naloxone (THN) is only available in Germany and Estonia, but peer distribution is not permitted in those countries. In Belgium, Finland, and the Netherlands, Naloxone can only be prescribed by medical professionals and administered by medical staff. As naloxone can be a lifesaving tool, the extended administration and distribution of (intranasal) naloxone should be considered. THN should be combined with ongoing attention towards education and training to prevent overdoses.

One of the major shortcomings of Estonia is that the field of addiction treatment has been a low national priority. Consequently, the number of trained professionals in the field is insufficient, national curriculums for health care workers are not focused on drug use disorder, there are limited possibilities for continuing education in this field, and there are no incentives in place to motivate specialists to work with this target group. This low interest is also reflected in the poor motivation of psychiatric clinics to work with PWUD, especially considering that there is an acute deficit of psychiatrists in Estonia.

Germany started scaling up THN programs after 2016, and they are currently available in 19 cities. The distribution of THN is closely linked to overdose response training events at low-threshold facilities or spaces for user self-. Distribution is hampered by a lack of clarity regarding the financing, as THN programs are not integrated into regular healthcare provision. In an emergency, the administration of naloxone by third parties

[2] See the annexed country report for more details.

is legally allowed under the "Justifying Emergency" (EMCDDA, 2020). The main challenge is that only a medical doctor can prescribe naloxone. Thus, a doctor's involvement in one form or the other in all naloxone training is needed, limiting the implementation of THN projects. As only people diagnosed with opioid dependency can receive a medical prescription, access to naloxone for non-users (family and friends) remains a problem (EMCDDA, 2020).

In the Netherlands, THN programs are not considered necessary at present because of good ambulance coverage and rapid response.

A THN and buprenorphine example from Finland: THN programs are not available in Finland. Naloxone works best in overdose situations with the use of short-acting opioid agonists. The most commonly misused street opioid is buprenorphine, a long-acting opioid. There is no data on the doses and frequency of administration of naloxone or whether intranasal naloxone works at all with buprenorphine overdoses. However, it has been argued that the distribution of naloxone could still be useful, e.g., in rural areas where it takes a long time for first aid to arrive (Rönkä & Niemelä, 2020).

Challenges and needs in health systems preparedness and how to address them

- THN should be widely available to people who use opioids, opioid-using peers, family members, significant others, and relatives.
- It would be beneficial to allow nurses and nonmedical staff (harm reduction, shelters, etc.) to independently provide naloxone.
- More education and training to prevent overdoses is needed.
- Better access to naloxone for people released from prison is essential, given that the risk of overdose is much higher after release from prison. For example, in Estonia, people who are released from prison are reluctant to ask for naloxone kits because this would imply continued drug use (which is particularly problematic for people applying for an early release). There are currently no possibilities to access naloxone for people who do not wish to share their personal information and identify themselves as opioid users, relatives, or potential bystanders.
- There is a need for intensified data collection and evaluation of the nonmedical use of prescription opioids.
- Pharmacies could provide take-home Naloxone (in nasal or other easy administration modes) to the layman or peer consumers. Experts recommend additional naloxone provision in order to be better prepared. This is currently not being practiced in the Netherlands. It is mentioned that this is not required because of good ambulance coverage (accessibility of 95% within 15 mins).

3.2.1 Prescription opioids

The United States has experienced three waves of the opioid crisis over the past two decades. The first wave was mostly related to prescription opioids, the second to heroin, and the third to highly potent synthetic opioids such as fentanyl. Therefore, it is essential to prevent the illicit use of prescription opioids and carefully consider the risks of using prescription opioids alongside their benefits.

Challenges and needs in the prescription practices and how to address them

- Health initiatives regarding the (illegal) use of prescription opioids are necessary, as problematic use of prescription opioids is expected to increase.

- Some preventive actions are targeting people who illegally use prescription opioids (e.g., initiatives to increase awareness among doctors, pharmacists, and relatives of patients), but there is still a long way to go.
- The reluctance of pharmacies to refuse to supply a medicine—pharmacies have the right to refuse to supply a medicine if there is reason to suspect that it is being abused.
- There is a need to develop measures to prevent the abuse of opioids while keeping effective pain management available for those patients who need them. This calls for a balanced approach to avoid an abrupt halt to treatment so that people would not seek their opioids elsewhere. To be able to decide on the most suitable treatment, physicians need to be aware of potential misuse, know the patient's situation, the current guidelines and types of pharmaceuticals and treatment options, etc.

Examples of good prescription practices

- **Opioid Taskforce (The Netherlands):** The main objectives are to limit the prescription of pain medication where possible and reduce the number of patients who engage in the long-term use of prescription opioids.
- Physicians in Germany need to attend a 60-hour course on substance use and addiction medicine to be allowed to prescribe opioids for patients.

3.3 Law enforcement

In recent years, the increase of NPS on the European drug market and the emergence of online drug markets (with drugs being delivered by postal services) have created new challenges for law enforcement.

Internationally, United Nations conventions control drugs to protect public health, based on identified risks as assessed by the World Health Organization. NPS pose a challenge because new variants, with only small changes in their chemical structure, are continuously developed to escape the legal frameworks. New variants also have the ability to evade toxicological tests, making their detection and monitoring increasingly difficult.

There is a need for increased investment to support specialist investigation capacities. European countries are often faced with significant gaps regarding resources and skills to conduct investigations of darknet drug markets. Many authorities also lack experts who have a technical understanding of cybercrime investigation and practical expertise in combating drug-related crime. Therefore, there is a need to invest more in interinstitutional cooperation and composing multidisciplinary teams for detection, investigation and prosecution. Moreover, law enforcement depends on collaborations with private companies such as post and courier services, mobile service providers, payment providers, and technology companies. Collaborating with these actors is critical in developing more efficient monitoring and adequately tackling the phenomenon.

Example from Estonia:

Rise and decline in fentanyl-related deaths in Estonia

Estonia has had an opioid epidemic going on for nearly two decades and has the highest overdose mortality rate in Europe. Due to the long history with SOs, law enforcement has also developed a good understanding of the synthetic opioid problem and the handling of the substance in seizure procedures. After two major seizures in late 2017 and early 2018, the Estonian police considered their preparedness and intelligence on

the drug market to be on a good level. The emergence of isotonitazene was discovered quickly. After the seizures, different fentanyl analogs emerged again on the market, but due to good knowledge of the situation, the police managed to interrupt the new distribution networks even before getting confirmations of these new SOs from the Estonian Forensic Science Institute.

Although the availability of SOs has decreased, there has not been a significant decrease in the number of active users, according to the police. This means the criminal networks still have the ambition to restore the market situation. Collecting intelligence about SOs and suppressing criminal organizations are still a high priority. The risk of the situation worsening is still high.

Despite the fact that SOs have also been seized in the mail (e.g., ordered from China), the police still consider them to be mainly trafficked in the "traditional" way (i.e., through criminal networks). Policing is also made easier by the fact that, unlike other substances, the local distribution of SOs has not yet moved to social media. This could also be attributed to the low popularity of SOs among adolescents. Therefore, it is important to collect information on SOs in every part of intelligence collection.

In Estonia, there are no new methods planned by the police at the moment. The police will continue their existing activities. Since the availability of SOs is limited, there is no pressure on them to implement new approaches. Further emphasis will be put on monitoring social media and the darknet. Even though SO distribution hasn't moved there yet, it has to be under constant scrutiny.

3.3.1 Darknet

The Internet has changed the drug markets, and it has become a key platform to offer all types of illicit goods and services. The darknet provides an ideal environment for the distribution of all types of illicit commodities, including drugs. In addition to the darknet, there are also other marketplaces where people can trade illegal substances, such as the clearnet and social media platforms like Snapchat, Facebook, and Instagram.

In Belgium, even though law enforcement experts find it important to monitor the darknet, they report not having enough capacity for this. More proactive investigations are deemed crucial, and more resources and expertise are needed on this specific topic. One of the rapid ways of (internal/police) communication is the newsletter, SOCNEWS (developed by the Federal Police). For instance, when isotonitazene appeared in online drug markets, a newsletter was sent to alert police officers, which included information on the substance, safety precautions they could take when encountering isotonitazene, and what to do in case of an overdose. However, although this newsletter was spread across different forums of the federal and local police, respondents noticed that not all police officers receive this information. This can be dangerous if not every police officer is aware of how to handle a certain drug overdose or NPS/substance found on the spot.

Challenges and needs in the law enforcement sector and how to address them

- The lack of resources is problematic. There is a lot of information available, and more could be done, but due to the limited resources, actions need to be postponed.
- The suitability of information systems for analytical purposes could be better.
- The analytical needs have to be taken into account in a better way when developing new information systems.
- The international exchange of intelligence is often too slow.
- Differences in legislation on controlled drugs between countries may cause challenges.

- Police officers are not receiving all relevant information regarding possible threats.
  Surveillance of the darknet and clearnet is an important tool in detecting new substances and drug trends.

Examples of good practices in the law enforcement sector

- Police newsletters—e.g., the previously mentioned SOCNEWS in Belgium—for widespread communication on new harmful substances.
- Example from Finland: The Police, Customs and Finnish Border Guard's (PTR) Cooperation. The PTR cooperation between the police, Customs, and the Finnish Border Guard aims to address crossborder crime and organized crime.[3]
- Example from Estonia: For a few years, the NGO Estonian Association of People Who Use Psychotropic Substances (LUNEST) has been making a monthly report to NIHD on the situation in the drug market and matters related to services. This report is also shared with the police. Information for this report is gathered all over Estonia—from PWUD, services (including mobile harm reduction units), partners, and NGOs. Harm reduction services exchange information with NIHD (National Institute for Health Development), LUNEST, and other NGOs. Viljandi Hospital's rehabilitation centers forward information gathered from clients to NIHD, the police, and other services.[4]

3.3.2 Legal responses to NPS

When a new psychoactive substance appears on the market in an EU country, legislators choose whether to bring it under control of the drug laws. There are a variety of control methods available in different countries, including analogic and generic systems.

Estonia

In Estonia, since 2016, narcotic drugs and psychotropic substances can be scheduled by groups to control the spread of NPS. If it is suspected that a new substance has emerged on the market, it is the police's priority to seize it as fast as possible and identify it with the help of EFSI. During the last few years, the number of emerging NPS has decreased, and the police do not consider them a top priority at the moment.

A weakness in the current system of narcotics control is that the whole process is time-consuming. For example, scheduling isotonitazene that does not belong to an already scheduled group took too much time. The police had information on the traffickers, but they couldn't act legally. After seizing the substance and identifying it through expertise, they should have returned it. Although it is not a frequent problem, they wish to be more effective than the current bureaucratic system allows—for example, a measure to impose a temporary ban on handling a substance until further analysis is done.

In addition, the waiting time for substance examinations is too long. The police's actions are always reactive based on that. There is a need for a more direct way of exchanging information with the PWUD that would help them identify a new hazardous substance whenever it emerges on the market. Information exchange

[3] PTR is the Finnish acronym for Police, Customs, and the Border Guard. See the annexed country report for more details about PTR cooperation.
[4] See the annexed country report for more details

could also be improved internationally, especially with neighboring countries. This would prevent situations where a substance that is wreaking havoc in a country is unscheduled in a neighboring country.

Belgium

Belgian experts stress the benefits of a generic law because it regulates the most common NPS—both existing and future ones encompassing several chemical classes—without updating the list of controlled substances every time a new one emerges. However, some bottlenecks are mentioned, such as the need for an update of the substances that are not yet covered by the generic law (such as isotonitazene).

Another recommendation is the decriminalization or depenalization of the possession of certain types of opioids or implementing experiments/practices based on the example of the provision of pharmaceutical heroin through pharmacists. It might reduce the need for other synthetic alternatives.

Finland

There is no generic classification model in place in Finland. Instead, the substances are assessed and added to the regulations individually. This policy is justified by the fact that citizens must be able to know in advance, in a precise and clear manner, which substance is banned and which is not. It must also be possible to know

whether it is a drug or a psychoactive substance banned from the consumer market, especially because the Criminal Code of Finland has adopted different positions towards different substances.

The Finnish classification system is not without fault, but it is clear-cut and fast. On the other hand, in the generic classification model, it is not possible to know without chemical expertise which substance is banned in the country and which one is not. The Finnish model is also capable of proactive monitoring because we can classify positional isomers for known substances, even if the isomer has not yet been detected in Finland or Europe. In Finland, a separate assessment of adverse effects and risks is carried out for each substance. Only after the evaluation will a decision be made on the classification of the substance.

Germany

From the German respondents' point of view, the NPS legislation in Germany is a lengthy bureaucratic process that jeopardizes harm-reduction interventions in this country. The police staff needs special training on NPS and especially on SOs. As mentioned previously, each state in Germany has its own rules and regulations regarding drugs and drug control. Besides, Germany is a member of the "Schengen" agreement with no border control within the Schengen area. However, special drug search systems in places where passengers or goods enter the country (e.g., airports and harbors). Such investigations cover all kinds of drugs rather than only NPS or SOs. However, not all checkpoints are equipped with modern equipment. Some interviewees suggested that legalization or regulation of substances was one of the options to control the harms of SOs and avoid imprisonments.

The Netherlands

The Netherlands will soon implement new legislation in which entire groups of NPS will be banned rather than continuing to add single substances to the list of controlled drugs. Similar types of NPS laws have been in force in Belgium, the UK, Austria, Hungary, Croatia, Ireland, Sweden, and Germany. The main concern regarding this law is that the generic ban in the Netherlands will cover fentanyl-type opioids but not other

synthetic opioids. However, fentanyl-like opioids have recently been decreasing in the EU, while non-fentanyl SO (like U-47700) have been increasing, probably because of the new tight legal restrictions in China. Vigilance and good monitoring will be key to not missing a new trend.

Challenges and needs in NPS legal responses and how to address them

- Scheduling is still too slow and bureaucratic. This jeopardizes timely harm-reduction interventions. A quicker path for scheduling new substances has been taken up in many EU member states in recent years.
- The waiting time for substance assessment is too long.
- Not enough checkpoints are equipped with modern equipment. Police staff needs more special training on NPS and especially on SOs.
- Also, for legal purposes, information exchange needs to improve internationally and especially with neighboring countries.
- Adding single substances to the list of controlled substances is considered time-consuming and reactive. More and more countries are adopting generic laws that ban groups of substances. Even if the generic approach is effective in making substances illegal, it does not solve problems related to the use.

3.4 Early warning systems

The EMCDDA is active in monitoring NPS, which may pose a serious public health threat to the population at large. Early Warning Systems (EWS) share information on NPS throughout Europe.

When an NPS is detected for the first time, for example in Customs, the EU Member States inform each other through the EMCCDA and its Reitox network and the European Union Agency for Law Enforcement Cooperation (Europol) and its national units. If Europol and the EMCDDA find that the information they are given requires the collection and analysis of more information, they will publish a joint report that is delivered to the European Council, the European Commission, and the European Medicines Agency (EMA).

The main challenge is that the international EWS system has not been developed to be rapid. If the use of SO increases in Europe, rapid communication and local early warning systems are crucial. Of the five project countries, only the Netherlands has improved its rapid alert system.

Challenges and needs in EWS and how to address them

- The main challenge is that the international EWS system has not been developed to be rapid.
- There is a need for a more direct way of targeting and exchanging information with the PWUD that would help them identify whenever a new hazardous substance emerges on the market.
- Reaching different user groups with relevant information requires finding out and establishing the appropriate channels. This should be done before the SOs enter the market.
- There is a need to keep investing in visibility through information exchange and sending rapid alerts—not only regarding the speed of information but also to make sure that all relevant partners receive the necessary information.
- There should be more exchange of information between the drug service centers and the law enforcement sector.

- Darknet drug markets may potentially provide a platform for the delivery and exchange of specialist, drug-related information, and advice.
- There is a need to invest in information exchange and sending rapid alerts—not only regarding the speed of information but also to make sure that all relevant partners receive the necessary information.
- There is a need to stay updated on the newest trends involving the clearnet and social media, the darknet, etc. This includes closely monitoring the ways drugs are distributed while also using these technologies as a tool for harm reduction.
- One good option for rapid alerts and information-sharing could be digital interventions, such as the use of apps, for alerting people who use drugs about highly potent or potentially harmful substances, adulterants, substances sold under a different name, and fake medication.

Examples of good practices in early warning systems

Dutch National Early Warning System

Drugs Information and Monitoring System (DIMS) is a national network of 31 locations across the Netherlands where substances can be submitted for drug-checking and one part of DIMS is to gain insight into the market for illegal drugs, monitor trends, and warn consumers about possibly dangerous substances on the market and associated health risks.

- **Red Alert**

Part of the monitoring and early warning system in the Netherlands is the possibility to announce a public warning, the so-called "Red Alert." Red Alert is a national or regional warning if there are signs of unusual harms or risks caused by specific drugs. The warning starts a procedure of rapidly performed identification and warnings, including an app-based consumer notification. The Red Alert system operates under the responsibility of the Ministry of Health, and the procedures are protocolized.

There are three situations in the Netherlands that can initiate a Red Alert:

1. When drugs with a serious health risk have been offered and identified at one of the drug checking facilities.
2. When the police or National Forensic Institute (NFI) finds hazardous drugs.
3. When local medical authorities report serious incidents with drugs.

- **Belgium Early Warning System (BEWS), Eurotox, and VAD**

The Belgian Early Warning System (BEWS) collects and disseminates information about the composition of drugs within a network that includes the RFPs, laboratories, hospitals, police services, the Federal Agency for Medicines and Health Products, and the Federal Government Department of Public Health, Food Safety, and the Environment. The BEWS is the result of adopting the Joint Action on New Synthetic Drugs by the Belgian government in 1997. The core tasks of the BEWSD are:

1. To monitor the composition of known illicit drugs (such as heroin, cocaine, MDMA)
2. To follow up on dangerous trends in the composition of tablets/powders
3. The fast detection of NPS in Belgium

4. To assess the risk of NPS for the general population (such as symptoms, toxicity, side effects)
5. To formulate recommendations for policy and/or prevention.

In addition to the national BEWS, there are two regional early warning systems: Eurotox manages the French community, and VAD manages the Flemish community. While the BEWS is responsible for monitoring trends in the composition of drugs seized by police services, the regional EWS, i.e., Eurotox and VAD, focus on prevention and harm reduction strategies.

- **Action plans and guidebooks for a synthetic opioid crisis**

In Belgium, action plans and guidebooks have been drawn up, similar to a guidebook drafted for pandemics, including setting up risk assessment groups, a crisis cell, and a crisis center when a synthetic opioid crisis might occur.

4. Conclusions

All five countries reported that illicit SOs are not currently a significant public health threat. Therefore, most countries have not been planning on implementing any special or new methods, operation models, or protocols to prepare for possible increases in SOs.

However, given existing shortcomings in the monitoring, data collection, and early warning systems (particularly in rapid communication), there is room for improvement in strengthening strategies to prepare for a potential SO crisis.

Two major concerns are the overprescription and possible diversion of pain medication in the Netherlands, Germany, Finland, and Belgium. It is often unclear how many people develop a dependency on prescription opioids, and there is a lack of insight into who or how many people use prescription opioids illicitly. Many European countries have reported significant increases in prescription opioids over the past decade, causing increasing concern.

Stigmatization of PWUD among health and social care workers continues to be an issue, even among some physicians and psychiatrists working in the addiction field. Although psychiatric and drug treatment clinics are obliged to treat patients with substance use disorders, they are often rejected. Therefore, it is important to increase the knowledge among professionals—particularly general practitioners—about substance use disorders. By reducing the stigma, people may be encouraged to seek the support and help they need.

Investing in diverse and evidence-based treatment and harm reduction interventions for opioid use disorders is important. Additionally, there is a growing need for comprehensive plans on monitoring and preventing SO-related overdose deaths.

In conclusion, to date, there is a very limited international exchange of information and good practices on SOs. However, many countries do have good practices at the national level. These practices should be shared, reviewed, and adopted in other European countries. Based on what has been presented in this report, we have identified a set of key recommendations related to SO-preparedness.

5. Recommendations

Given the fact that SO are not yet causing major problems In Europe, this is the right moment to get wellprepared. Once SO enter the drug market, the momentum will be gone. In what follows, we list a set of recommendations for European countries on how to become better prepared for the increase in the availability and use of potent SO.

Monitoring systems

- Countries should invest in more scientific research on NPS and online drug markets and include SO as a distinct category in surveys.
- Preparedness strategies should be informed by consumer-level information.
- Drug-checking services can provide valuable information on new substances and other changes in the drug market. The faster the new or dangerous substances are identified, the sooner the public can be warned.
- There is a need for coordinated and comprehensive monitoring (with multiple sources and multisectoral input) of the availability and use of NPS (including SO) in different populations (e.g., people with problematic drug use and the general population).

Health systems

- Take-Home Naloxone should be widely and easily available to people who use opioids, their family members, significant others, and relevant professionals.
- Nurses and nonmedical staff (harm reduction, shelters, etc.) should be allowed to provide naloxone to enhance its availability.
- Education and training to prevent overdoses should be provided at a low threshold.
- Naloxone should be readily available to people released from prison, as the risk of overdose is much higher right after the release from prison.
- Better efforts are needed to monitor the nonmedical use of prescription opioids.

Law enforcement

- Law enforcement should focus on supply reduction, including disruption of drug trafficking and trade controls and improving surveillance against drug trafficking.
- There is a need to invest more in inter-institutional cooperation and composing multidisciplinary teams for detection, investigation, and prosecution.
- Law enforcement should collaborate with relevant parties, such as post and courier services, mobile service providers, payment providers, and technology companies.

Early Warning systems

- Enhancing the rapid flow and exchange of information is key to national and international SOpreparedness.
- Rapid alert systems (such as the Red Alert) are excellent ways to inform and warn the public of potentially harmful substances.

- Monitoring the darknet, clearnet, and drug fora is a cost-effective method for monitoring drug use, distribution, and other trends. These technologies can also be used as a tool for harm reduction.

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Annex I: Instructions and guiding questions for the interviews to develop the 5 country reports

SO-PREPAREDNESS IN FIVE COUNTRIES

GOAL: IN-DEPTH ANALYSIS OF SO-PREPAREDNESS OF THE PROJECT PARTNER COUNTRIES (FIN, NL, EE, DE, BE)

BACKGROUND

In Europe, highly potent synthetic opioids (SO) and related overdoses are a growing health threat. SO-PREP is a two-year European project focusing on strengthening health systems' preparedness to timely and effectively respond to increases in the prevalence, use, and harms of Synthetic Opioids. The term "synthetic opioids" refers to any prescription and nonprescription (semi-) synthetic opioids, such as fentanyl and fentanyl analogs, tramadol, methadone, and U-4770.

The main aim of SO-PREP is to contribute to the enhancement of the SO-related preparedness of the European Member States to effectively monitor and respond to SO-related health risks, hazards, and harms.

The objectives of the project are to:

- gain a better understanding of the *illicit use* of synthetic opioids and related health needs in Europe;
- strengthen national health systems' synthetic opioid preparedness; and
- develop an evidence-based toolkit for implementing enhanced SO monitoring and response capacity.

SO-PREP is coordinated by the Trimbos Institute (NL), and the project partners are:

- Correlation—European Harm Reduction Network (NL)
- Estonian National Institute for Health Development (TAI)
- Finnish Institute for Health and Welfare (THL)
- Frankfurt University of Applied Sciences (DE)
- Ghent University (BE)

THL (Finnish Institute for Health and Welfare) is collecting in-depth information on existing practices of national SO-PREPAREDNESS in five countries: FIN, NL, EE, DE, BE. Each of those five countries organizes **online** group (or individual) expert interviews from the fields mentioned below to assess the national and local capabilities of existing detection and preparedness models for a potential SO crisis.

The experts to be interviewed will be chosen from the following fields/institutions/organizations:

- ✔ Forensic institutes/relevant laboratories
- ✔ Reitox national focal points

- ✓ Law enforcement sectors: police departments, customs, border forces
- ✓ Health care services: ambulance/hospital emergency departments
- ✓ Poison settings
- ✓ National Medicines Agencies
- ✓ Local commissioners and providers of services for people who use drugs
- ✓ NGOs, low-threshold services

The questions relate to several topics such as the preparedness of health systems, law enforcement, and local authorities and partners regarding synthetic opioids—how they may need to scale up to be better prepared for increases in the use and harms of synthetic opioids.

The planned timing for the interviews is October–November 2020, and each country provides a brief summary (report) of the interviews by the end of January 2021.

The purpose of these interviews is to explore existing national or local strategies and models of preparedness for dealing with a potential synthetic opioid crisis in Europe.

The aim is to identify and address gaps in national and local SO-PREPAREDNESS and

strengthen the response capacity of health systems for preparedness and response planning for a potential opioid crisis in Europe.

The term "preparedness" refers to the ability of governments, professionals, and communities to anticipate and respond effectively to a potential or current spread of synthetic opioids in order to timely and effectively protect people from harm.

GUIDELINE FOR EXPERT MEETINGS

Structure of the final report:

1. **Monitoring systems** (1–2 pages)
2. **Health systems** (1–2 pages)
3. **Law enforcement** (1–2 pages)
4. **Conclusion** (1 page)

Structure of each of the 3 topics:

- Current situation: what's available/what's being done/what's working
- Weaknesses/ challenges/what's not working in the current way of working
- Needs: how to move forward/how to become better prepared, i.e., what is needed if we have to deal with a crisis in the future Plan/timeline:

- Each partner writes up a report about their own country. No transcriptions of interviews are needed.
- The country report is due for submission to THL: Tuukka/Inari by the **end of November**.

Methodology – two options. Choose the option that seems more feasible to you.

- Three groups with 3–5 experts to cover the three topics above ○ For example, an online group discussion with 3 experts on monitoring systems
- Individual interviews, if group discussions are not feasible ○ For example, if there is a risk that individuals will not feel comfortable to speak freely in a group.

Interview questions:

- Ask **monitoring** experts about:
    - Data collection
    - Early warning systems

- Ask **health** experts about:
    - Health system preparedness ○ Prescription opioids

- Ask **law enforcement** about:
    - Law enforcement ○ Narcotics control

Ask the experts in-depth questions about their two topics. Then also ask cross-topic about perceived needs regarding other systems and cooperation with other professional actors involved (e.g., ask health system experts about needs regarding monitoring data).

INTERVIEW GUIDE – QUESTIONS THAT MAY BE HELPFUL DURING THE INTERVIEWS

1. MONITORING SYSTEMS/DATA COLLECTION/DETECTION

- What methods of rapid data collection for detecting the illicit use of synthetic opioids (or for other drugs/substances) are currently being used in your country? These might include forensic institutes and relevant laboratories, causes of death, substance use testing (e.g., urine, blood, saliva, hair), driving under the influence, police and customs drug seizures, syringe residue analysis, wastewater analysis, hospital emergency data (e.g., overdose-related emergency department visits), fieldresearch, or others.
- In your opinion, what is working, what is not working, and what kinds of challenges or shortcomings are there in the rapid data collection methods mentioned above?
- How could these challenges and shortcomings be addressed?
- How is the cooperation organized between monitoring services/EWS and relevant professional partners?
- Needs: how to move forward / how to become better prepared

2. PREVENTION AND HEALTH SYSTEMS' PREPAREDNESS

How are the health care services prepared for (possible changes in) the use of synthetic opioids?

- What preparedness methods/operation models or protocols are currently being used in health care services (e.g., emergency care, ambulance) to respond to the use of synthetic opioids (e.g., staff training/briefing guides for first responders)?

- What preparedness methods/operation models or protocols are needed to respond better to possible increases in the use of synthetic opioids (e.g., staff training/briefing guides for first responders)? Are you currently planning on implementing new methods?
- How is the cooperation organized between health care services and relevant partners?
- What is working, what is not working, and what are some of the challenges and shortcomings in preparedness in health care services? How could these challenges and shortcomings be addressed?
  - Needs: how to move forward / how to become better prepared

ILLICIT USE OF PRESCRIPTION OPIOIDS

- How could the illicit use of prescription opioids (nonmedical use of prescription drugs) be prevented? What methods or protocols are currently being used for possible increases in prescription drug misuse (e.g., responsible prescribing of opioid medications, prescription drug monitoring programs, state-run electronic databases, others)?
- Are you currently planning on implementing new methods?
- What are some of the challenges and shortcomings in preventing prescription opioid misuse?
- How could these challenges and shortcomings be addressed?

3. LAW ENFORCEMENT SECTOR AND PREPAREDNESS (focus on supply-side drug control)

- How is the law enforcement sector prepared for possible changes in the synthetic opioids market (including synthetic opioids sold on darknet markets)? What **preparedness methods/operation models or protocols** are currently being used in the law enforcement sector (e.g., police, customs, border forces, others) to tackle possible increases in the synthetic opioid supply (e.g., law enforcement guidelines, intelligence programs, darknet investigation units)? Are you currently planning on implementing new methods?
- What is working, what is not working, what are some of the challenges and shortcomings in preparedness in the law enforcement sector?
- How could these challenges and shortcomings be addressed?
- How is the cooperation organized between law enforcement and other relevant partners to tackle the supply of synthetic opioids?
- Needs: how to move forward / how to become better prepared

NARCOTICS CONTROL

- New substances enter and old ones exit the market continually (e.g., NPS and new synthetic opioids, fentanyl and its chemical variants or analogs). How is the control of SO organized in your country? *How could those new harmful substances, which have not yet been classified as narcotics, be brought under control faster than at present?*

4. LOCAL EARLY WARNING SYSTEMS

The following questions refer to the action plan and rapid flow of information that occurs when an increase in the use of synthetic opioids is detected.

- The National Early Warning System on NPS does not identify or respond/provide local alerts on new drug trends. How are the local drug alerts organized in your country (e.g., rapid drug alerts to specific target audiences, professionals, and service users)? Do you have any rapid communication systems or local early warning systems in place to provide alerts on new drug trends (e.g., real-time alerts, information bulletins, mobile applications for new potent harmful adulterants when new substances are identified, substances sold under the name of another drug, fake tablets, fentanyl sold as heroin, etc.)?
- Who are the relevant partners and authorities involved in communications and warnings of potential increases in synthetic opioid use (e.g., hospital emergency departments, paramedics, police, drug services, homeless services, forensic services, poison information centers, clubs, and others)?
- What could be the advantages and challenges of developing a national/local early warning system (NEWS /LDEWS)? What could be achieved with NEWS/LDEWS? How could the information be coordinated, implemented, and reported? And how would the information be provided to the media?
- What are the challenges and shortcomings of current information exchange methods? How could these challenges and shortcomings be addressed?

Annex II: Country Reports

Trends and in-depth information on synthetic opioid preparedness in Belgium, Estonia, Finland, Germany, and the Netherlands

Deliverable D3.4 Country Reports

This report is part of the project SO-PREP, which has received funding from the European Union's Criminal Justice Programme. The content of this report represents the views of the authors only and is their sole responsibility; and does not reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made

Funded by the Criminal Justice Programme of the European Union

Country Report Belgium

Colman Charlotte

Kochuyt Justine

November, 2020

INTRODUCTION

For about a decade, an increasing number of new psychoactive substances (NPS) are appearing in Europe. Most of these NPS include synthetic cannabinoids and cathinone (Blanckaert et al., 2020). Synthetic opioids, and more specifically AH-7921, appeared around 2012 especially for sale on online drug markets. Starting from 2014 however, increasing numbers of these synthetic opioids, including fentanyl-analogues, appeared online as well (Blanckaert at al., 2020).

These new synthetic opioids pose a particular public health concern due to their high potency, easy accessibility through online drug markets, and possible distribution into the regular street opioid supply, where they might be mixed with or substituted for heroin (Cannaert et al., 2018).

Its high potency, its low dose required to gain the desired outcomes, the continuous change in chemical structure, the resilience of the organisations involved in its supply, pose challenges for all actors involved, from the users themselves to clinical and forensic toxicologists, monitoring agencies, health agencies and law enforcement actors (Cannaert et al., 2018)

The research “Strengthening Synthetic Opioids health systems’ preparedness to respond to the potential increases in prevalence and use of Synthetic Opioids” (SO-PREP) is a two-year project, funded by the European Union, focusing on strengthening national health systems’ preparedness across Europe to timely and efficiently respond to increases in the prevalence and harms of synthetic opioids. More specifically

evidence-based toolkits will be developed to enhance the monitoring and response capacity regarding synthetic opioids.

This Belgian country report relates to work package (WP 3) of the SO PREP research. This Belgian country report aims to sketch a first light on the prevalence of synthetic opioids in Belgium and aims to assess, in a general way, the existing detection and preparedness models for dealing with synthetic opioids and a possible, potential, crisis.

METHOD

In this report we refer to 'synthetic opioids' as to the **non-medical use of synthetic opioids** i.e. any **(semi-) synthetic opioids used in an illegal setting.**

As such synthetic opioids could be distinguished into three categories:

a. NPS-opioids (fentanyl-derivatives + others, e.g. U-47700)

b. Fentanyl

c. Prescription opioids if acquired in an illegal setting (e.g. oxycodone, diverted OST medication)

The main emphasis of this report is, however, on the category of non-prescription synthetic opioids but when the prescription opioids (used in an illegal setting) are mentioned by our respondents this will be included as well.

We interviewed four experts in the areas of monitoring, health services and law enforcement. The respondents have been chosen based on their expertise in one of these domains and their knowledge regarding synthetic opioids. All interviews took place between October and November 2020 and lasted between one and two hours. An informed consent was signed. The interviews were recorded, transcribed and analysed using Word.

Domain	Respondent
Monitoring and early warning	Interview 1
Health (prevention, treatment and harm reduction)	Interview 2
	Interview 3
Law enforcement	Interview 4

Additionally some experts in the field of monitoring have been contacted informally to fill some gaps.

We want to emphasise that this report does not aim to provide a comprehensive overview but rather sheds an **explorative qualitative light** on this phenomenon and related preparedness from a Belgian point of view. Given the limited time, we have interviewed one (occasionally two) respondents in each domain.

Furthermore, the expertise on this topic in Belgium is limited, partly due to the fact that (estimated) use of illicit synthetic opioids is low.

RESULTS

First, we present an overview on the general evolution in prevalence before discussing the current situation in each domain i.e. monitoring/early warning, health systems and law enforcement. For each domain, we will focus on the state of the art regarding synthetic opioids. Furthermore, we will focus on the weaknesses and challenges, as identified by our respondents, on how to move forward and become better prepared when we have to deal with a synthetic opioid crisis in the future.

Prevalence of (new) synthetic opioids in Belgium 2014-2018

From 2011 until 2015, the prevalence of NPS was rapidly increasing in Belgium but has been decreasing since. Between 2014 and 2017 around 90 to 100 new NPS were detected each year. In 2018, around 50 new NPS were detected. 80-90% of these substances have been detected by customs laboratories, stressing the role of Belgium as a distribution country[5].

The prevalence of (new) synthetic opioids on the Belgian illicit drug market is a more recent phenomenon as first samples of synthetic opioids have been detected around 2015. The confirmed substances included U47700, MT-45, AH-7921 and fentanyl-analogs such as ocfentanil and carfentanil. Nevertheless, the share of synthetic opioids in the total number of NPS is rather low. In 2015, when most NPS have been detected in Belgium, only 3 out of 120 new NPS were synthetic opioids. In 2016, 4 out of around 100 NPS, in 2017, 6 out of around 90 NPS and in 2018 2 out of around 50 NPS were newly detected synthetic opioids[6].

Important to state is the fact that, until 2018, possibly due to the easy synthesis of NPS opioids, combined with the stable online availability of precursors, most synthetic opioids were fentanyl-analogues. Between 2018 and 2019 the number of newly detected U-compounds increased, while only one new fentanylanalogue was found. This could be related to the introduction of a new legislation in China in 2019[7] in order to control fentanyl-related substances[8]. However, in August 2019 a sample, obtained during routine online monitoring of drug markets by the Belgian Early Warning System Drugs (BEWSD), identified the sale of the NPS opioid Isotonitazene[9], "*which is the first detected member of a new benzimidazole class of opioids"* (Blanckaert et al., 2020 pp. 2). This substance is not new, but was first reported in 1957. The most potent compound of the benzimidazole class is etonitazene with an estimated potency of hundred to a thousand times that of morphine (Blanckaert et al, 2019). The toxicity of Isotonitazene has however not been extensively studied but "*pharmacological evaluation of Isotonitazene using a MOR activation assay confirmed that this substance is a strong opioid. This, combined with fact that our data indicate that this compound was being sold undiluted, represents an imminent danger to anyone aiming to use this powder*" (Blanckaert et al., 2020, pp. 8). Today, Isotonitazene has not been regulated yet[10] (see infra generic law).

[5] Interview 1

[6] Interview 1

[7] These Chinese government banned the production and sale of fentanyl and many of its variants in May 2019

[8] Interview 1

[9] Interview 1

[10] Interview 1

In sum, the estimated illicit use of synthetic opioids in Belgium seems to be low. According to several of our respondents this could be due to the stable supply and high quality of other illicit drugs.[11] It is however generally known that the potency of these substances can be high to extremely high. Synthetic opioids have already caused many deaths throughout the world, including some in Belgium. Between 2015 and 2017 Belgium experienced several fatal overdose cases after consuming synthetic opioids, mainly fentanyl, but also U-47700, carfentanyl, acrylicfentanyl, ocfentanyl led to fatal overdoses. Between March and July 2017, five drug-related deaths have been reported related to injecting or sniffing synthetic opioids such as U-47700, ocfentanyl, acrylfentanil or carfentanyl. Important to mention, is that in most cases, it was assumed that the victims acquired these synthetic opioids through online drug markets (i.e. darknet drug markets) and were known as drug users (some recreational other had a history of what could be considered as substance use

disorders[12]). At least one case involved mislabeling, in which a young man thought he was using a particular drug, but it turned out to be fentanyl (Interview 1).

> *In March 2015, a 17 year old man was found dead in his home. He had a history of drug addiction. Drug paraphernalia were found in his proximity such as a brown powder, a ziplocked plastic bag. Autopsy findings and toxicological analysis concluded an acute intoxication with ocfentanyl. The manner of death was assumed to be accidental after snorting the powder. The substance was purchased over the internet (Coopman, Cordinnier, De Leeuw & Cirimele, 2016)*
>
> *In January 2016, a 30 year old man was found dead. Drug paraphernalia were present on the table such as an envelope delivered from China, a white powder, a digital scale and a spoon. The person was known as an illicit drug user who experienced with online drug purchases. His search history revealed searches for carfentanil and U-47700. The toxicological analysis revealed traces of fentanyl and U-47700 (Coopman, Blanckaert, Van Parys, Van Calenbergh & Cordonnier, 2016).*

All respondents concluded that, today, they assume there's no significant problem with nonprescription/(new) synthetic opioids (i.e. NPS opioids, fentanyl (analogues)) in Belgium because its estimated use is low. All respondents also concluded that they assume that **no problem or crisis similar to the opioid crisis I the US will occur with non-prescription synthetic opioids in the near future**.

[11] Interview 1; Interview 3

[12] Based on the limited amount of information available [13]
An MSOC is a….

"… we just do not see any fentanyl or fentanyl derivatives … to give an example: 'In the past six months, since the start of the first lockdown, we have been collecting (heroin) samples from different MSOCs[13] *with the specific intention to verify whether fentanyl or fentanyl derivatives are present in the heroin chain in Belgium. But up till today, we haven't detected any heroin sample in which we have found fentanyl or any other synthetic opioid. I assume that the quality of heroin in Belgium is high (enough) and that users aren't looking for the new NPS opioids (…) and furthermore, Belgium is (almost) the only country in the European Union that has a generic law on fentanyl and fentanyl derivatives … so far all the fentanyl analogs and NPS fentanyl derivatives are covered by our generic law and thus illegal"*[13]

This does not mean that no harms have been related yet with non-prescription synthetic opioid-use in Belgium. As mentioned earlier, between 2015 and 2018, several Belgians tragically died of a synthetic opioidrelated overdose which could be related to online drug purchases. If Belgium faces a synthetic opioid problem, this remains undetected.

"If" we face an NPS opioid problem in Belgium, it is quite invisible or hidden because we believe it mainly happens by individuals, who purchase their opioids online and not by the typical heroin street user shifting from heroin to NPS opioids because of the price or legal issues or others motivations. In contrast to what we see abroad, our (Belgian) heroin is not contaminated with fentanyl of carfentanyl but we keep following it up"[14]

While the non-medical use of synthetic opioids is estimated to be low, the respondents do mentioned **a possible increase in the (illicit) use and misuse of prescription synthetic opioids in Belgium.**

Insert data RIZIV (this would be data on the illicit use of prescription SO (such as forged prescriptions). I was told that I person x could give insight in this (difficult-to-access) data, but unfortunately person x hasn't responded yet. Not sure whether we have to wait for it. Maybe something to discuss with the team.

I. Early Warning System and Monitoring

[13] Interview 1

[14] Interview 1

In the following paragraph we will describe the current situation regarding the Belgian Early warning system and other monitoring means, before discussing in short some weaknesses and challenges related to the monitoring of synthetic opioids.

Early Warning System

In Belgium we have a Belgian Early Warning System on Drugs (BEWSD). The BEWSD is the result of the adoption of the Joint Action on New Synthetic Drugs by the Belgian government in 1997[15]. Initially, the BEWSD was one of the registry systems of the service 'illicit drugs', department of epidemiology, hosted by Sciensano; in 2020 however, the BEWSD has been split from the service 'illicit drugs' and functions now as a distinct unit within Sciensano.[17]

The core tasks of the BEWSD are: (1) To monitor the composition of known illicit drugs (such as heroin, cocaine, MDMA,) (2) To follow up on dangerous trends in the composition of tablets/powders (3) The fast detection of NPS in Belgium (4) To assess the risk of NPS for the general population (such as symptoms, toxicity, side effects) (5) To formulate recommendations for policy and/or prevention[16]

In addition to the national BEWSD, there are two regional Early Warning Systems: Eurotox manages the French Community, VAD manages the Flemish Community.[17] While the BEWSD is responsible for monitoring trends in the composition of drugs seized by police services, the regional EWS, i.e. Eurotox and VAD, focus on prevention and harm reduction strategies.

BEWSD receives the results on the analysis of drug samples through toxicological and clinical-biological laboratories, customs services, police and public prosecutor's office. These analyses are usually based on (seized) drug samples such as tablets and powders. Nevertheless, biological samples such as blood or urine can also be involved in the analyses.[18]

The procedures to be followed to inform the BEWSD about new, high-dose or high-risk substances (except for cannabis) have been laid down in two Royal Decrees (2003 and 2006).[19] The law of 7 February 2014 changing the "law of 24 February 1921 concerning the trafficking of poisonous, soporific, narcotic, psychotropic, disinfectant or antiseptic substances and substances which can be used for the illicit manufacture of narcotic and psychotropic substances" adds the obligation for all Belgian laboratories to automatically send the analysis results to the BEWSD, even if they are part of a judicial investigation.[20] This obligation also indicates that if the labs do not report on a daily basis, they might lose their license for

[15] https://drugs.wiv-isp.be/drugs-info/Illegal-drug-use/New%20and%20high-dosed-substances/Pages/default.aspx [17] Interview 1
[16] https://drugs.wiv-isp.be/drugs-info/Illegal-drug-use/New%20and%20high-dosed-substances/Pages/default.aspx
[17] https://drugs.wiv-isp.be/drugs-info/Illegal-drug-use/New%20and%20high-dosed-substances/Pages/default.aspx
[18] https://drugs.wiv-isp.be/drugs-info/Illegal-drug-use/New%20and%20high-dosed-substances/Pages/default.aspx
[19] https://drugs.wiv-isp.be/drugs-info/Illegal-drug-use/New%20and%20high-dosed-substances/Pages/default.aspx
[20] https://drugs.wiv-isp.be/drugs-info/Illegal-drug-use/New%20and%20high-dosed-substances/Pages/default.aspx [23] Interview 1

narcotics. Of course, 'daily' is not possible in practice, but it does ensure that labs communicate more quickly.[23] After this implementation, the data exchange has tremendously increased.

If deemed necessary, the BEWSD then sends an 'alert' to the professional network. This network consists of all laboratories, emergency services, police and public prosecutors, drug treatment services in Belgium.

The information received about NPS is recorded in a specific database that is electronically accessible to registered experts.[21] Based on this information, the BEWSD reports annually on the purity of the various illegal drugs, drug intoxications and any deaths that may be linked to drug use.[22] Moreover, this information is shared with international partners, including EMCDDA, Europol and UNODC.[23]

The BEWSD is, according to one of the respondents, experiencing **some challenges** today due to issues relating to (1) structural organisation, (2) staff organisation, skills and knowledge gaps (3) resources and (4) visibility[24].

(1) Belgium is a federal state, composed of communities and regions. This structure may complicate the organisation of the early warning system and the spread of the alerts. The BEWSD fits under the federal competence, while prevention and harm reduction are regional competences. As such, there is fragmentation in tasks and responsibilities, that might lead to delays in information exchange. The cooperation in general between BEWSD and the regional Early Warning Systems (VAD and EUROTOX) is considered as good i.e. a positive working climate to discuss good and bad practices regarding their way of working. Nevertheless, the respondent mentioned working points, such as the above mentioned speed in performing the work and in disseminating relevant information.

(2) Regarding adequate skills, knowledge and expertise, it was mentioned that within the current BEWSD team, only one person has a toxicological/pharmacological background. When this expertise would disappear, the entire system might collapse. Until a couple of months ago, the BEWSD consisted of only one person, which is perceived as not sufficient according to our respondent. In the meantime, however, an additional, PTE has been employed.

(3) In combination with the previous comment, there is not only a lack of (experienced) staff but also a lack of financial and IT resources. There is a need to invest more in ensuring that each laboratory registers its results (from the analysis) electronically, so this information can reach BEWSD immediately. At the moment this process is considered burdensome. Although the registration happens systematically, due to the renewal of the system, there are a number of problems, such as delays.

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[21] https://drugs.wiv-isp.be/drugs-info/Illegal-drug-use/New%20and%20high-dosed-substances/Pages/default.aspx and interview 1

[22] https://drugs.wiv-isp.be/drugs-info/Illegal-drug-use/New%20and%20high-dosed-substances/Pages/default.aspx

[23] https://drugs.wiv-isp.be/drugs-info/Illegal-drug-use/New%20and%20high-dosed-substances/Pages/default.aspx

[24] Interview 1

(4) Today BEWSD must invest more in its visibility towards their target audience. Recently, an employee has been hired, who will disseminate important information of the BEWSD through social media.

The respondents however mention that, despite the above mentioned challenges regarding resources and organisation, they stress that **they will be ready when facing a possible problem with synthetic opioids.** It was emphasised that whenever a crisis with synthetic opioids might arise, all the (small) problems will be left aside and the whole team will immediately do everything they can to tackle the problem, as a team. Furthermore, action plans and guidebooks have been drawn up, similar to a guidebook that has been drafted for pandemics, including setting up risk assessment groups, a crisis cell and a crisis center when such a crisis might take place.

> *If a crisis occurs, we are ready for it and we know what to do. (…)*[25]

Other data collection and monitoring means

Additional information on the extent of NPS use and more specifically, synthetic opioid use, in Belgium is obtained from, amongst others:

- **Surveys** such as the online Belgian Global Drug survey (coordinated by Van Havere, T) focusing on a subgroup of the Belgian population i.e. younger, more experienced drug using populations, the Drug Syringe Exchange survey (coordinated by Windelinckx, T) focusing on users of the syringe exchange locations; the Health Information Survey (coordinated by Sciensano) focusing on the general population; ➔ In most cases, synthetic opioids are included in a broader category and not specifically mentioned in a distinct category. During the analysis however, synthetic opioids could be specifically selected (what happens on a yearly basis to monitor any changes) but in most cases, it is not specifically mentioned in the analysis/reports due to the fact that its prevalence is that low.
- **Drug checking services f.e.** Modus Vivendi (Walloon part of Belgium) is part of the Trans European Drug Information project (TEDI). TEDI is a network of European fieldwork Drug Checking services sharing their expertise and data within a European monitoring and information system. Its main goal is to improve public health and intervention programs with analytical data. To achieve this goal, TEDI has developed a database that collects, monitors and analyses the evolution of various European drug trends in recreational settings. When an unknown product emerges in Belgium, it is possible to call upon this network and verify whether other participating countries are familiar with the substance and can share their experiences.[26].
- **Wastewater analysis** is only an indicator for certain opioids such as methadone, oxycodone and could not make a distinction between medical or non-medical use. Synthetic opioids such as fentanyl

[25] Interview 1

[26] https://idpc.net/fr/alerts/2013/05/t-e-d-i-network-a-step-forward-for-european-drug-checking-services, 17/12/2020

are difficult to retrieve by wastewater analysis due to their micro doses and its low prevalence in Belgium i.e. the concentrations of these substance residues in wastewater are often below the lower limit of detection;

- **Scientific research** on NPS, including synthetic opioids (for example Van Havere, Vander Laenen, Colman, Gremaux, Blankaert, Simonis & Van Dijck (2020). Understanding New Psychoactive Substance (NPS) use in Belgium from a health perspective, financed by the Belgian Science Policy Office)
- Treatment Demand Indicator (TDI): TDI is one of five key epidemiological indicators to collect and report core data on the number and profiles of those entering specialised drug treatment each year. Also, here, due to the low prevalence, synthetic opioids are included in the category "other" and not included in a distinct category. However, it is analysed and monitored on a yearly basis. If its use would increase, the analysis will show it.
- Information on **drug seizures** (see law enforcement).

Based on these parameters (by means of surveys i.e. the use of synthetic opioids; seizure data i.e. the supply of synthetic opioids and treatment demand indicators i.e. treatment entering data) relevant actors gain insight in the estimated prevalence of illicit (non-prescription) synthetic opioids Belgium. Today, the analysis of all these parameters indicate that the estimated illicit use of (non-prescription) synthetic opioids is low. As such, there are no reasons to extend the monitoring of (non-prescription) synthetic opioids.

Although most of these monitoring tools do not present synthetic opioids as a distinct category, its use is (yearly) analysed and monitored. As such, if an increase or change in its prevalence would happen, relevant actors will detect it.

II. Health systems (prevention, treatment and harm reduction)

In the following paragraph, we will describe the current situation regarding the Belgian health system related to illicit synthetic opioids, in which we focus on prevention, treatment and harm reduction before discussing in short some weaknesses and challenges within this domain.

Although this report initially intended to solely focus on non-prescription synthetic opioids, this section will also focus on some challenges related to the (illicit) use of prescription synthetic opioids. Some of the challenges mentioned in this regard, could be extended to dealing with non-prescription synthetic opioids as well. We will adequately indicate whether the examples provided by our respondents relate to illicit use of prescription or non-prescription synthetic opioids.

As mentioned earlier, related to the fact that the illicit use of synthetic opioids is estimated to be low, **health providers are not confronted a lot with people solely using/being addicted to illicit synthetic opioids such as NPS opioids/fentanyl (analogues).** The respondents indicate that in their daily practices (i.e. low threshold centers, treatment services) they are mainly confronted with people (illegally) using prescription synthetic opioids. Within this group, we distinguish two subgroups in health services: (1) people who are already using opioids in an illicit way and start looking to illegally obtain prescription synthetic opioids because it is cheaper or because they want to experiment with it; (2) people who legitimately use prescription synthetic opioids but later proceed to abuse them and become addicted to them.

We could be brief about the first group i.e. **the group that illegally uses non-prescription synthetic opioids** such as NPS opioids or fentanyl. One of the respondents indicates that currently, prevention, treatment and harm reduction in the area of non-prescription synthetic opioids is quasi non-existent or not specified as its use is not common in Belgium. As such, no specific preparedness method or operation models specifically targeting non-prescription synthetic opioids were mentioned. One of the respondents indicated that at the

moment, health initiatives towards people using synthetic opioids are not considered a priority[27]. For example: most prevention campaigns focus on classic opioids such as heroin, rather than on NPS opioids. In low threshold treatment services, we'll especially encounter the group of people already using opioids, such as heroin, who occasionally uses synthetic opioids such as fentanyl or oxycodone. They receive treatment for their primary opioid-related problem (i.e. heroin). As such, the regular, existing health services are used when dealing with this group of users. However, some respondents mentioned the need to explore the broader implementation of naloxone and strengthening training to enhance the health system preparedness (see infra).

Regarding the second group, i.e. the **group that (illegally) uses prescription synthetic opioids**, the respondents provided more information. Health initiatives regarding the (illegal) use of prescription synthetic opioids is deemed necessary, as the respondents assume increasing problems related to this today.

The respondents indicate that although some preventive actions, specifically targeting this group of persons (illegally) using prescription synthetic opioids, exist, such as initiatives to increase awareness among doctors, pharmacists, relatives of patients, we still have a long way to go in this area.

Generally speaking, regarding health, we lack concrete tools to tackle the problems related to this second group. One of our experts was able to inform us about a few problems, including a lack of knowledge regarding substance use disorders leading to doctors being too ignorant or rather too strict about prescribing opioids, and difficulties to divert this group from the general practitioner's office to specialised (drug) treatment services. This causes further problems, including stigma.

> *"I am involved in a couple of actions and workshops to raise awareness, especially among doctors and pharmacists. The problem is that I often see a black and white story (…). Some don't go to these workshops because they are not interested. But also amongst those who are present, you often notice some sort of skepticism: "what should we do?", "Pain centers are full and patients are asking for it". There is also another group, being very strict and who don't to or dare to prescribe opioids anymore. (…). There is a too little knowledge regarding substance use disorders (…)"*[31]

In most cases and when some preconditions are fulfilled, pharmacists have insight in all medication a client has bought. As such, they have a clear overview on prescription practices and in some cases, an indication of possible misuse. Some of these pharmacists take up their red flag function in case of possible misuse and inform the prescribing doctor.

[27] Interview 2

Interview 3

Pharmacists are often caught between two sides. Pharmacists are willing to take up their red flag function, but I also know that when they contact the doctor (about a particular prescription of a

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client), that's not always appreciated. In other words: doctors are saying "why are you interfering, it is my prescription practice""[32]

Some opt to implement a more strict controlling system in Belgium: for example patients are only allowed to see one pharmacist, applying strict control, by strengthening the use of a blacklist.

I see some issues with this proposal. In certain areas "blacklists" are applied when dealing with so called shoppers. When someone is on that black list (…): it seems ok, but that actual person is on the streets, without (medication).

In general, it can be concluded that according to our respondents some **safety nets are lacking, as well as management and leadership** i.e. it remains important that professionals, and general practitioners in particular, keep on taking up their responsibility by, not only, following up on these patients (rather than solely stopping prescribing opioids or reacting in a repressive way by putting patients on a "black list") and divert him/her – if possible- to specialized, evidence-based (!) treatment but also by lifelong learning and educating themselves about substance use disorders (and synthetic opioids).

The reasons for intake across this group of persons (illegally) using prescription synthetic opioids could be roughly distinguished in three groups: some of them start treatment based on their own motivation, others because of a judicial diversion (because of theft or they are caught using a forged prescription), or a diversion from their general practitioner.

When formulating **recommendations**, consideration can be given to better screening of synthetic opioid disorders and adequate referral to specialist, evidence-based treatment. Furthermore, it was mentioned by one of the respondents to extend the centers specialized in treating opioid disorders.

Regardless of any group of synthetic opioid users, when looking at the health sector, including harm reduction organisations, the respondents indicate that most of these agencies are **cooperating well** with each other (to name a few: modus vivendi, drug checking projects, Eurotox, Sciensanco, Boule de Neige, Quality Nights, Safe and Sound).

Nevertheless, two respondents mentioned **some challenges in this area**, that could complicate tackling a possible synthetic opioid crisis in the future.

Interview 3

The mentioned challenges relate to a lack of resources (financial and organisational means), or the need to make better agreements regarding dealing with personal data (yet providing integrated care) or the fact that a lot of activities are based on the goodwill of people involved (f.e. Quality nights has to motivate places where parties are organised to actively work with them).

Another challenge that was mentioned was the fact that it is not possible yet to distribute Naloxone (as an injection) in Belgium. Today, only specialised staff could administer naloxone in the injected form. A non-

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professional is not allowed to administer naloxone, as this would involve the illegal practice of medicine. Several respondents therefore recommend to make naloxone available in nasal spray and distribute it through pharmacies.

> *We are really in favour of making that (Naloxone) available to users. It's a shame that this is not yet possible in Belgium. Because we really believe that, the American and Canadian examples show this, it can save lives*[28]*.*

> *I would love to see Naloxone, distributed by pharmacies, in a nasal spray. As such, everyone who wants to buy such a nasal spray, could buy it, opioid user or not*[34]*.*

Another recommendation mentioned in this area by some respondents, is thinking about the decriminalisation or depenalisation of the possession of certain types of opioids or implementing experiments/practices based on the example of the provision of pharmaceutical heroin through pharmacists. Although there would always be people who don't want to be part of such a government system, it might reduce the incentive to look for synthetic alternatives according to one of our respondents.

III. NPS legislation and law enforcement

In the following paragraph, we will describe the current situation regarding the legislation of NPS in Belgium, before discussing in short some weaknesses and challenges of this legislation. Afterwards, we will focus on how law enforcement is dealing with the supply of illicit synthetic opioids and their current challenges in this regard.

[28] Interview 2

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Interview 3

NPS legislation

Until 2014, the control of NPS was achieved by amending the list of controlled substances. In 2014, the law was adapted to allow generic group definitions of controlled substances to be listed. In September 2017, Belgium opted for a new, generic legislation targeting NPS (Royal Decree of September 2017). Several respondents stress the **advantages** of the generic law. The main advantage being that most common NPS are now included, both existing and future ones encompassing several chemical classes, without having to update the list of controlled substances every time a new one comes along.

Interview 3

In addition to this, the Chinese government banned the production and sale of fentanyl and many of its derivates in May 2019. One of our respondents assumes that this recent ban has resulted in a significant reduction in the country's illicit fentanyl trade and availability of fentanyl in countries worldwide, including Belgium. However other substances pop up, such as **isotonitasene**. In one year, at least 7 new opioids popped up within this class. This substance has not been included yet in the Belgian generic drug law, although they are currently working on a generic definition of this class, in order to update the Belgian generic drug law.

Although several respondents stress the benefits of the generic law, especially for tackling the NPS supply, **bottlenecks** are mentioned as well. First of all, it was mentioned that an update is required for those products not covered yet by the generic law (such as isotonitasene). Second, relating to the above mentioned update, is the doubt of one of the respondents whether the inclusion of new structures will have a lot of effect, as producers do find ways to bypass these regulations. Third, it was mentioned that the generic law could be complex and difficult to understand for persons without any chemistry expertise.

> *It (the generic law) could be complex (…). However, I do believe that it is a good instrument for (law enforcement) to tackle the problems regarding synthetic cannabinoids and synthetic cathinone and all substances covered in the generic law. But I do know that an update is needed. But I am also certain that this generic law has been a major tool to help fighting the NPS supply (…) although NPS is not our biggest problem in Belgium*[29]

Law enforcement, focusing on NPS supply

Just like the other respondents, the respondent interviewed from law enforcement, indicates that currently**, there are no indications of a problem related to (the supply of) illicit synthetic opioids.** Regarding the possession and trafficking of non-medical synthetic opioids, our respondent confirms that they (i.e. federal police, NICC and customs (lab)) only occasionally encounter (samples of) synthetic opioids. Also, the proportion of synthetic opioids seized (within the total proportion of NPS, opioids and /or other illicit drugs) is small.

The respondent indicates that in Belgium, there is a good cooperation between all services involved in tackling NPS supply. In fact, recently, a platform has been installed to organise a quarterly consultation between different experts, who inform each other about the latest novelties in the area of possession and supply of illicit drugs. In this consultation several organisations are involved including FAGG, customs laboratory, NICC, BEWSD/Sciensano, Cell precursors, federal police, as well as legislative experts in case a legislative issue occurs.

[29] Interview 4

> *This is an ideal platform for all partners involved… it did not exist before (…) it is some sort of network in which we communicate in a fast way with each other: we know each other, we could ask each other questions and answer them directly*[30]

As mentioned earlier, the generic law is specifically mentioned as an advantage for law enforcement actors, yet some challenges might arise as discussed above i.e. an update of the generic law is needed and the generic law could be complex to understand for those without any knowledge of chemistry (see supra).

Furthermore, there are various investigation methods to tackle the supply of synthetic opioids. Traditional investigation methods can be used, such as pseudo shopping, but also special investigation methods could be used such as interception of mail, interception operations, direct eavesdropping, delayed intervention; and collection of data on bank accounts and bank transactions.

The respondent mentions that if we might be confronted with a crisis related to the production and/or trafficking of synthetic opioids, law enforcement (police and judicial authorities) will be aware of the urge to tackle it and take the necessary actions. The above mentioned methods seem to be sufficient according to the respondent.

Our respondent however also mentions that most illicit synthetic opioids are obtained from the online drug markets, especially from purchases through darknet drug markets.

> *On Research Chemicals* [31] *you will mainly find substances like synthetic cannabinoids and cathinone but not fentanyl or synthetic opioids.*[32]

When it comes to darknet however, the respondent mentions a **challenge**.

> *Several international organisations continuously monitor the darknet. We (Belgium) do not have the capacity to (…) monitor the Belgian supply of synthetic opioids nor other illicit drugs on the internet and the darknet. And that is a weakness. We should have at least one to two persons at the central department who continuously monitor online drug markets. (…) as long as we don't have a clear insight in the Belgian side of the story, (…) we cannot convince a prosecutor (…) to start an investigation"*

Darknet markets adapt quickly and law enforcement should follow. However, Belgian law enforcement actors are mainly working in a reactive way, while they indicate that more proactive investigations are deemed crucial as well as more resources and expertise are needed on this specific topic.

[30] Interview 4

[31] A website on the clear net

[32] Interview 4

Another challenge that was mentioned, was the need to make sure that every police officer receives all relevant information regarding possible threats. Today, one of the rapid ways of (internal/police) communication are newsletters i.e. SOCNEWS (developed by the Federal Police). For example, when isotonitazene popped up on online drug markets, a newsletter was sent to alert police officers, including information on the substance, some safety precautions they could take when they (suspect to) detect isotonitazene and what to do when they suspect an overdose related to isotonitazene "*Because of this it seems useful to highlight some aspects of 'Isotonitazene' especially to (re) sensitize our colleagues which safety measures one must take when being confronted with these highly potent synthetic opioids, such as fentanyl and isotonitazene*" (SOCNEWS, 3/2020, pp.1).

However, the respondent mentions that although this newsletter was developed quickly and has been spread across different forums (of the federal and local police), they noticed that not every police officer receives this information. This might be dangerous as not every police officer might be aware of how to handle a certain drug overdose or NPS/substance that has been found on the spot.

CONCLUSION AND RECOMMENDATIONS

Based on this explorative small-scale study, we might summarise that currently the estimated prevalence and use non-prescription (new) synthetic opioids (i.e. NPS opioids, fentanyl (analogues)) in Belgium is low. Respondents indicate that in general, heroin samples in Belgium are not mixed with synthetic opioids, that the quality of heroin is high (enough) and that users aren't looking for substitutes (i.e. new NPS opioids).

Answering the question "*are we ready if a significant problem with (illicit) synthetic opioids would occur (in the near future)*?", most respondents indicated that they, given the above mentioned reasons, do not assume this will happen in the short term, but if it happens, that they feel confident they could handle it. Action plans and guidebooks have been drawn up, similar to a guidebook that has been drafted for pandemics, including setting up risk assessment groups, a crisis cell and a crisis center when such a crisis might take place. As one of the respondents stressed: ***If a crisis occurs, we are ready for it and we know what to do[33].***

Nevertheless some overarching recommendations could be formulated.

I. Keep on investing in monitoring illicit synthetic opioid use in the general population

Although the current estimated prevalence of synthetic opioids in Belgium is low, it remains important to monitor its use. Such knowledge is crucial to design adequate policy interventions for both the supply and demand side of synthetic opioids.

[33] Interview 1

In general, no specific challenges have been mentioned with the monitoring of synthetic opioids. Although Belgian drug monitoring services/tools do not specifically focus on synthetic opioids in their data collection and analysis (i.e. in surveys the category "synthetic opioids" is not always inserted as a distinct category), respondents indicate that the evolution in the use of synthetic opioids is analysed on a yearly basis, based on several indicators i.e. use in the general/specific populations, treatment indicators and supply indicators.

It is however also important to stress that the true extent of (non-medical) use of illicit synthetic opioids in Belgium might be underestimated because of the fact that these compounds are not always included in all drug monitoring services/tools f.e. waste water analysis (Cannaert et al., 2018) and because of the hidden use by individuals purchasing these illicit substances from online drug markets (see next recommendation). Following the tragic death of some Belgians overdosing on synthetic opioids, it became clear that some of these substances were mislabeled, i.e. the victims not knowing they were taking synthetic opioids. This only becomes clear AFTER a sample has been sent to a lab for further testing. As such, one of our respondents confirms the possibility that "*we might have rather insight on the intoxications and fatal overdoses related to synthetic opioids than on the (non-medical) use of synthetic opioids in the general population, because it is so hidden"*.[34]

We therefore recommend to further intensify the ongoing monitoring actions, to invest in scientific research on NPS and online drug markets and if possible, to consider including "synthetic opioids" as a distinct category in surveys.

Furthermore, another challenge that was mentioned across all domains, was the need to keep on investing in information exchange and sending rapid alerts: not only regarding the speed of information but also to make sure that all relevant partners receive the necessary information.

II. Improve online drug monitoring in order to design adequate policy interventions

Building on the previous recommendation, it is notable to mention that all registered synthetic opioid-related deaths in Belgium might be linked to online purchases, mostly from darknet drug marketplaces (Interview 1, Coopman et al., 2016a; 2016b).

Evolutions visible on online drug markets, may elicit our knowledge on synthetic opioids, including modus operandi, new classes popping up (such as isotonitazene), the quality of the substances, distribution and marketing strategies. Efficient knowledge gathered through monitoring and analysis could identify and guide evidence-informed practices for both the demand and the supply side, such as specifically targeting vendors selling high risk substances at several markets (Broséus, et al., 2016) or designing tailor-made harm reduction information. Both drug demand and drug supply recommendations should not be considered as opponents, but rather as complimentary actions in our Belgian integral and integrated drug policy.

[34] Interview 1

Improving supply disruption

First, there is a need for increased investment to support specialist investigation capacities. Currently, European countries -including Belgium- are often faced with significant gaps regarding resources and skills

for conducting investigations on darknet drug markets. Many authorities also lack experts who have both a technical understanding of cybercrime investigation as well as a practical expertise in combatting drugrelated crime. Therefore, there is a need to invest more in inter-institutional cooperation and composing multidisciplinary teams for detection, investigation and prosecution. Second, law enforcement actors cannot handle this new and upcoming phenomenon alone. The success of their actions often depends on collaborations with private companies such as post and courier services, mobile service providers, payment providers and technical companies. Engagement with these actors is becoming more important, not only to develop a more sufficient and up to date monitoring but also to tackle the phenomenon in an adequate way (Colman, Bronselaer, Devresse et al., 2020).

Improving harm reduction initiatives

At the same time, there is a need to include a balanced approach, by not only focusing on tackling the drug supply side but also by responding to (possible) negative aspects on the demand side. Furthermore, some authors argue that the actual law enforcement strategy of taking down markets is not cost-efficient in reducing darknet drug market's illicit drug trafficking (Décary-Hétu & Giommoni, 2016).

The monitoring of these darknet drug markets could help prevention and treatment organisations to better understand (online) drug use, including synthetic opioid use, and as such develop more adequate demand reduction responses (Thanki & Frederick, 2016).

Darknet drug markets may potentially provide a platform for the delivery and exchange of specialist, drugrelated information and advice, although evidence for the effectiveness of such approaches is currently limited and research methodology is under-developed (Sumnall, 2017). There have been established practices, for instance the case of dr. Fernando Caudevilla, also known as 'DrX', who has been openly and actively practicing different kinds of harm reduction on dark web drug platforms for years, including sharing information, advice and drug-testing services. Other initiatives exist as well, such as the recently developed "online drug helping tool" (drughelp.eu, Pompidou Groupe Council of Europe), which could also be shared on these forums. This self-reporting tool provides an overall assessment of the possible risks related to drug use. It also shares information about where a user can turn to in order to get support if he/she want to recover from drug use. It could be recommended to extend this tool specifically targeting the use of synthetic opioids, if deemed crucial in the future (Colman, Bronselaer, Devresse et al., 2020).

Furthermore, when potentially dangerous substances or bad practices are shared online, it might even be possible to leverage the cryptomarket trust system, by actively approaching and interacting with these vendors or cryptomarket administrators (Lamy et al., 2020). By a practice of spreading "alerts", it might be possible to use the cryptomarket key features to reduce the negative excesses caused by certain darknet drug market sales. The example of Energy Control/DrX illustrates this practice. They asked users to send samples they bought from cryptomarkets to test their components. On a certain moment, their drug checking services detected samples containing fentanyl. After contacting the administrator of that particular market, the vendor got immediately banned from that cryptomarket, illustrating the harm reduction potential by actively engaging with cryptomarket administrators (CND, 2020)

III. Strengthening health care services towards (synthetic) opioids

As mentioned by our respondents, health care initiatives specifically targeting people using non-prescription synthetic opioids are not considered a priority. For example, most prevention campaigns focus on classic

opioids such as heroin, rather than on NPS opioids. In (low threshold) treatment services, they will especially encounter the group of people already using opioids, such as heroin, who occasionally use synthetic opioids such as fentanyl or oxycodone. They receive treatment for their primary opioid-related problem (i.e. heroin). As such, the regular, existing health services are used when dealing with this group of users. It remains therefore crucial to further invest in diverse, evidence-based and well-resourced prevention, as well as treatment and harm reduction interventions for opioid use disorders.

In addition, other recommendations could be suggested, especially targeting the illicit use of prescription synthetic opioids. First it was recommended to increase the knowledge among professionals, in particular general practitioners, about substance use disorders. Second, to reduce the stigma associated with (synthetic) opioid disorders. This could include eliminating concepts like "opioid addict" in internal, official/external communication but also about supporting recovery, aftercare and inclusion in communities. Third, it was mentioned that management and leadership among general practitioners are needed i.e. by taking up their responsibility by, not only, following up on these patients (rather than solely stopping prescribing opioids or reacting in a repressive way by putting patients on a "black list") and diverting them to specialized, evidence-based treatment.

Another overarching recommendation mentioned in the interviews, for people using synthetic opioids in general, was the need to strengthen the use and distribution of (intranasal) naloxone. Naloxone can be lifesaving to many patients overdosing on opioids. Some studies suggest that "*intranasal naloxone has a strong evidence base as a first-line therapy for people with suspected opioid overdose in the prehospital setting*" (Karila et al., 2019, pp. 139). It is therefore recommended to study whether the extended administration and distribution of (intranasal) naloxone might be possible in Belgium taking into account possible side effects, medical and legal constraints. Of course, this should be combined with an ongoing attention towards education and training to prevent overdoses.

Additionally, it might be useful to know more about the profile of persons using synthetic opioids in order to design appropriate health interventions. Furthermore, these health services could adapt their modes of communication and develop new methods to reach this specific target group f.e. through darknet forums. Using scientific input, a demand reduction strategy might then be formulated.

IV. The generic law: benefits and challenges

Several respondents, especially law enforcement actors, stress the benefits of a generic law. As such, most common NPS are regulated, both existing and future ones encompassing several chemical classes, without having to update the list of controlled substances every time a new one comes along.

However, some bottlenecks are mentioned as well, such as the need for an update for those products not covered yet by the generic law (such as isotonitasene) or the fact that the generic law could be complex and difficult to understand for persons without any chemistry background.

Recently, a Belgian study on the use of NPS has been published (Van Havere, Vander Laenen, Colman, et al. 2020). This study found out that professionals and users hadn't acquired substantial knowledge about the Belgian generic legislation on NPS. Therefore, the researchers recommended issuing more information about its content and implications through (online) formation or training, leaflets and online initiatives. It was also stated that:

It goes without saying that this innovative generic law enables law enforcement actors to better respond to this rapidly evolving NPS market from their point of view. At the same time however, scientific evidence stresses the potentially unintended consequences of prohibitionist laws and several European policy practices (UK, Ireland, etc.) that rely on such laws, includ(ing) specific, well-described exceptions and/or amendments.

The Belgian law (Royal Decree) has the benefit of clarity and its rationale, i.e. keeping legislation up to pace with rapidly emerging NPS, is relevant. The implementation of the generic law, though, is riddled with concerns; not in the least of a constitutional nature (Beltgens, 2017; Nutt, 2011). An example is the uncertainty about whether a future substance is subject to the law or not, potentially violating the right to 'due process'. (…) One thing we did find in our sample is that laws do not affect the (motivation for) use of the interviewees. 96% of our sample admits that the legal status of a drug is not related to current use (intention). This observation is not new and has been illustrated in many studies (a.o. Doessel & Williams, 2008; MacCoun, 1993; S. Taylor, Buchanan, & Ayres, 2016).[35]

In sum, more insight in the link between the (generic) legislation and NPS demand and supply is needed to ensure evidence-based responses.

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Country Report Estonia

1. Introduction

1.1. a brief overview of the problem in your country

In Estonia, the use of synthetic opioids (mostly fentanyl and its analogues) emerged in the early 2000s. For over a decade up to 2017, Estonia had the highest overdose death mortality rate in Europe and in 2010 to 2017, fentanyl was involved in 70-80% of overdose deaths. While diversion of controlled substances (including fentanyl) from health care system can occur, there is compelling evidence that recent national outbreaks of drug-related deaths are attributable to illicitly manufactured fentanyl. In addition, Estonia is among countries with the highest prevalence of people who inject drugs (PWID) coupled with a very high HIV prevalence among PWID (Uusküla, Talu, et al., 2020).

In the end of 2017 and beginning of 2018 Estonian law enforcement managed to dismantle multiple large criminal organizations and their fentanyl production sites. Since then, the availability of fentanyl and its analogues has been limited. This has led to a sharp decline in overdose related mortality rates: 2017 – 110, 2018 – 39 (34 related to opioids), 2019 – 27 (19 related to opioids) (NIHD, 2019; 2020). In addition to the

limited availability of fentanils, this decrease can be attributed to wider use of naloxone and new harm reduction programs including law enforcement arrest diversion. According to data collected from PWUD, many of the former fentanyl users have also started to use amphetamine and synthetic cathinones to compensate the lack of fentanyl (Siseministeerium, 2019).

1.2. Method: data collection and analysis

For this report 7 online expert interviews were conducted in November 2020. 5 interviews were individual and 2 involved 2 experts from the same institution/organisation. Experts represented the following institutions/organisations:

- Estonian Forensic Science Institute
- Estonian Police and Border Guard Board, Northern Prefecture
- State Agency of Medicines
- Viljandi Hospital
- Tallinn Emergency Medical Services
- NGO Convictus Estonia
- NGO Estonian Association of People Who Use Psychotropic Substances (LUNEST)

Questions were related to several topics such as monitoring systems/data collection, prevention and health systems' preparedness, illicit use of prescription opioids, law enforcement sector preparedness, narcotics control, and local early warning systems. First, all experts were asked in-depth questions about their main field of expertise. Then, questions and comments about other topics were asked. All the interviews were recorded with permission of interviewees and later transcribed. The report is structured according to the interview questionnaire and all information provided is based on the expert interviews (unless indicated otherwise).

2. Monitoring systems

2.1. Current situation: what's available/ what's being done/ what's working

The only laboratory in Estonia with a permission to handle controlled substances is the Estonian Forensic Science Institute (EFSI). According to EFSI, they analyze all seizures done by law enforcement and toxicological analysis (samples collected from persons and causes of death). Since 2019 they also started doing wastewater analysis. They emphasize that to get an accurate overview of the situation, all these methods must be used in combination. For example, in the first half of 2019 cocaine seizures were minimal in North Estonia, indicating very low availability, but in Tallinn wastewater analysis cocaine was 3rd after cannabis and amphetamine.

The prevalence of SO-s has been low in Estonia since 2018. After the large seizures law enforcement noticed many criminal attempts to fill the unmet demand – temporarily, a myriad of fentanyl analogues emerged on the market, but were seized. Isotonitazene was first detected by EFSI in the spring 2019, total of at least 7

seizures in 2020. Carfentanyl 13 seizures (104 grams). Para-methyl Acetyl fentanyl 1 seizure. Also, a single seizure of etazene. These amounts are about the same as 2019 and are considered very low.

EFSI shares information with different law enforcement agencies, National Institute for Health Development (NIHD), and State Agency of Medicines (SAM). Hospitals occasionally send samples that they weren't able to identify. EFSI see themselves well-prepared based on the 20 years of experience with fentanyls. They also cooperate with forensic laboratories in other countries when detecting new substances.

EFSI is the central knowledge hub for law enforcement agencies on narcotic and psychotropic substances. The police see their role in doing seizures and gathering intelligence about new substances on the market. They also work with people who use drugs (PWUD), but this information has limited use since their official strategies need to be based on official data received from EFSI.

For a few years the NGO Estonian Association of People Who Use Psychotropic Substances (LUNEST) has been making a monthly report to NIHD on the situation in the drug market and matters related to services. This report is also forwarded to the police. Information for this report is gathered all over Estonia – from PWUD, services (including mobile harm reduction units), partners, NGO-s. Harm reduction services exchange information with NIHD, LUNEST and other NGO-s. Viljandi Hospital's rehabilitation centers forward information gathered from clients to NIHD, the police and other services. However, all this communication is done informally and doesn't have any formal regulations.

On issues related to new psychoactive substances (NPS) the SAM also uses information received from EFSI. They receive a regular report every month. In addition, they find the European Database on New Drugs useful. Database is also used by NIHD and EFSI. Communication with pharmacies on prescription medication is working well, SAM receives a quarterly overview on sales of opioid prescription medication.

2.2. Weaknesses/ challenges/ what's not working in the current way of working

Although information exchange between mentioned partners isn't formally regulated, it is considered functioning. A shortcoming is that more partners (e.g. SAM, harm reduction services) don't have access to the LUNEST monthly report yet. In addition, LUNEST would appreciate more feedback regarding the uses of this report (e.g. how do law enforcement agencies use it or if some change in service delivery has resulted from their previous suggestions).

Another shortcoming pointed out by LUNEST is the lack of anonymous drug checking possibilities. According to Estonian laws, all controlled substances must be seized and processed by law enforcement. This means there is no legal option for a private individual to hand in substances for checking. However, without any evidence on the substances available on the market, it is difficult for users and NGO-s to provide credible information about new substances or the overall situation. It is a problem confirmed by the police, who see the need for a more proactive approach. The chemical composition of and risks associated with NPS need to be found out earlier in cooperation with people who use drugs. The current process that the police must follow – making a seizure, sending it to expertise, waiting for the result – is too time-consuming. Substances can spread during this time and all activities will only be dealing with the consequences.

EFSI does not see any larger challenges in the current situation, even though their workload is considered high: waiting time for analysis of seizures is 1,5 months, for toxicology 1-2 weeks. There are no other

laboratories that are authorized to do this work and they don't see the need for it in a country as small as Estonia.

The lack of a rapid communication system is pointed out also by Tallinn Emergency Medical Services (TEMS). They have informal communications with the police "in case of something unusual", but these cases are rare. It is emphasized that this warning system needs to be based on credible information.

According to the police the current system of communication is functioning in times of very limited SO availability. In case of a "new wave" (i.e. an increase in the prevalence of SO) the system's preparedness is doubted. The dissemination of information to the wider public is considered satisfactory but targeting messages on specific substances to specific groups is certainly still a challenge.

The national Early Warning System (EWS) on New Psychoactive Substances that was established in 2014 is currently in the proccess of being terminated. Additional comments on this were provided by NIHD. The main reason is underutilization – it was used rarely and only by NIHD, SAM and EFSI who already use other channels for communication. Neither law enforcement agencies nor health care services used the system and drug services like harm reduction sites operated by NGO-s weren't granted access to it. Another reason has been the decreasing number of NPS emerging on the market. Most of them are already covered by the Act on Narcotic Drugs and Psychotropic Substances and Precursors that since 2016 allows groups of substances to be scheduled and there is no need for rapid communication to implement new regulations. In addition, the European information system and database on new drugs (EDND2) that has been recently established to exchange information on NPS serves the same purpose as the national system (it is also accessed by the same institutions).

2.3. Needs: how to move forward/ how to become better prepared i.e. what is needed if we have to deal with a crisis in the future

Developing a working local EWS that could provide real time alerts would be a way to move forward. It would need to involve all the relevant partners: PWUD, services, NGO-s, NIHD, law enforcement agencies, EMS, SAM, EFSI and to a certain extent the public. Such a system would require a well-organized flow of information and a clear understanding of everybody's roles (including which information is relevant for whom to avoid information overload). Possibly it would need separate management to ensure that the provided information is competent and consistent.

A challenge here is that PWUD do not form a homogenous group that could be addressed as a single partner. It is a myriad of groups with different interests, needs and channels of communication. Finding out and establishing these channels is essential and should be done before a new crisis has arrived. It could be an interesting challenge for a small digitally advanced country like Estonia.

Although EFSI and SAM are not too enthusiastic over the need of a new local EWS (likely because of their experience with the previous national system), other experts see clear advantages in it. First of all, it could save lives, have a positive impact on individual and community health, while reducing social exclusion. More broadly, it would help improve quality of drug services, save resources and reduce the workload of different national systems.

3. Health systems

3.1. Current situation: what's available/ what's being done/ what's working

Tallinn EMS has a long and intensive experience with SO-s. No national statistics on emergency calls regarding drug overdoses are available, but Tallinn EMS has collected statistical data since 1998. The number of calls increased from 200 in 1998 to 1396 in 2017. Now there has been a sharp decline (350 in 2019) as a result of the limited availability of fentanils. Many of these calls are recurrent, reaching up to 15 calls in a year for the same person. Before SO-s and heroin, significantly less potent homemade opium poppy liquid was used that was harder to overdose. In 2001 naloxone was added to the standard ambulance equipment.

The ambulance working protocol foresees that emergency response center receives a call regarding a drug overdose, which means respiratory depression (highest priority). If on arrival opioid overdose is suspected, administration of naloxone is part of protocol.

EMS does not test substances. Diagnostics is based on clinical symptoms and response to the antidote. They always ask what the person used (they need to know drug slang) and consider their relationship with SO users rather good. There are more problems with users of other substances who try to hide and lie more about their use. The person is identified when possible and data including the diagnosis is added to the patient's electronic medical records where previous incidents can be seen. They estimate that about 80% of SO overdose calls were identified. In the early 2000s drug use was still criminalized and the police prosecuted people for substance use. Revoking this played an important part in building more trust between users and EMS. Paramedics also exchange information with harm reduction services which helps to get an overview of the situation and active users.

Since late 90s the ambulance operating protocols have been updated three times and are considered effective. The current ones are the result of intensive practice (over a thousand patients a year) over the last two decades. Dealing with overdose calls has been an "everyday drill" and no cases where they were late to the site or were not able to react in time for other reasons, resulting in an overdose death, could not be brought out by Tallinn EMS. Despite current low overdose numbers, new 2020 American Heart Association Guidelines for CPR and ECC will be implemented this year. This also includes a guideline for opioid overdose, but the methods mentioned there have already been used in Tallinn EMS.

EMS sees the police as their main partner with whom they have rapid communications in case of need. They also have a monthly briefing on the number of calls. At times, the police make inquiries about specific times and locations, but this was more frequent when there were more fentanils available. Cooperation is greatly valued – after the police started seeing the user as a patient instead of a criminal, people were less afraid to call EMS and they could reach more people. Understanding and sharing each other's goals is considered important.

There is not much cooperation with other regional EMS units. In case the opioid overdose is reversed successfully on site, no further hospitalization or tests are done. When administering naloxone is insufficient (e.g. the person has used other depressants in addition to opioids), the patient will be taken to hospital where more thorough tests can be done. In case of a traffic accidents or other kind of incident the collected samples will be sent to EFSI.

A proactive step has been the national overdose prevention programme since 2013 that targets opioid users, their close ones and drug service workers. The programme teaches how to recognize an overdose, administer naloxone and provides a naloxone kit while emphasizing the need to always call an ambulance. It is usually carried out in drug services.

The non-medical use of prescription opioids isn't considered problematic in Estonia. Misuse may be more prevalent among other types of prescription medication, but the use of opioids has been under very strict regulations. SAM monitors the use of prescription medicine in Estonia through quarterly statistics – how much has been imported, how much has been prescribed, what are the dosages. In addition, pharmacies are exchanging information with SAM directly to report on possible cases of misuse. Based on this overview a risk assessment can be done with further proposals for change where needed. When overprescribing is detected then by regulation restrictions are placed on prescribing frequency/amount to physicians. For example, it is currently planned to place over-the-counter painkillers containing a low amount of codeine (8 mg) under prescription because of potential misuse.

3.2. Weaknesses/ challenges/ what's not working in the current way of working

Naloxone is prescription drug in Estonia and is only available via the special national overdose deaths prevention program. There are no possibilities to have access to the antidote for people who do not wish to share their personal information and identify themselves as opioid users, their relatives or potential bystanders.

According to LUNEST, there is still stigmatization of PWUD among health care workers, even by some physicians and psychiatrists working in the addiction field. Although psychiatric clinics are obliged to handle patients with a substance use disorder, in reality they are often rejected.

According to Viljandi Hospital, the field of substance use has been a low national priority for a long time and the number of trained professionals in the field is insufficient. National curriculums for health care workers are not focused on drug addiction disorder and there are limited possibilities for continuing education in this field. In addition, there is no system in place to motivate specialists to work with this target group.

In addition, there is a lack of systematic cooperation between the health care and social welfare systems. When a service turns out to be unsuitable for a person (e.g. there are currently no specialized services for patients with dual diagnosis), there is no formal follow-up that would keep the person linked to services. It depends only on the good will of specialists to keep the person "on the radar".

The coverage of mental health topics in the media has seen an increase over the years. This has also increased the pressure on physicians to prescribe medication for different disorders. It is important that treatment would not limit itself to handing out medication but would include psychosocial components. It is important to have a wide range of treatment and support services available for the people who use drugs. According to the SAM however, there is also the challenge of underprescribing. Strong restrictions help to reduce misuse but that also reduce the availability of medicines for patients who need them. For example, Estonian cancer patients are currently underprescribed opioids. Utilization of prescription opioids in Estonia is considerably lower than in developed countries in Europe, the United States and Australia (Uusküla et al., 2020).

3.3. Needs: how to move forward/ how to become better prepared i.e. what is needed if we have to deal with a crisis in the future

Tallinn EMS considers their SO preparedness very high but as the availability of fentanils has been limited in the last few years, it is important not to forget the gained skills and knowledge.

Neither does SAM plan on implementing any new responses. They continue to do risk assessment and see need for development in improving methods that are already in use. SO preparedness is considered high. However, Estonia's low population size means that the market for pharmaceuticals is small and comercially unattractive for many producers. It requires constant work to ensure wider range of medicines, especially newer, is available in treatment.

According to Viljandi Hospital, preparedness could be increased by increasing the national priority of substance use disorders (e.g. more national training of specialists and better awareness on these issues among specialists working in other fields). In addition, there is a need for continuity of care and more efficient case management across services (i.e. formally monitoring patient pathway).

4. Law enforcement

4.1. Current situation: what's available/ what's being done/ what's working

After the major seizures in late 2017 and early 2018, the police consider their preparedness and intelligence on the drug market to be good. The emergence of isotonitazene was discovered quickly. After the major seizures different fentanyl analogues emerged on the market, but knowledge of the situation was high. This allowed them to interrupt the new distribution networks even before getting confirmations from EFSI.

Although the availability of SO-s has decreased, there has not been a significant decrease in the number of active users according to the police. This means that the ambition to restore the market situation remains for the criminal networks. Collecting intelligence about SO-s and suppressing criminal organizations remains a high priority. The risk for the situation to worsen is still high.

Although SO-s have also been seized in the mail (e.g. ordered from China), the police still consideres them to be mainly trafficked in the "traditional" way (i.e. through criminal networks). Policing is also made easier by the fact that, unlike other substances, the local distribution of SO-s has not moved to social media yet. This could also attribute to the low popularity of SO-s among adolescents. Therefore, it is important to collect information on SO-s in every part of intelligence collection.

Since 2016 narcotic drugs and psychotropic substances can be scheduled by groups to control the spread of NPS. For example, fentanils are scheduled as a group, but isotonitazene as a separate substance. In 2020 EFSI also detected etazene once, which is not scheduled, but they don't see the need to schedule the whole group yet. Changes to the schedules are proposed by the SAM based on their risk assessment and approved by the Minister of Social Affairs.

In case of suspicion that a new substance has emerged on the market, it is the police's priority to seize it as fast as possible and identify it with the help of EFSI. During the last few years, the number of emerging NPS has decreased and the police do not consider them a top priority at the moment. The situation with "traditional" substances is more problematic.

According to NIHD, in 2018 and 2019 naloxone trainings were provided among Tallinn and Ida-Viru police units. It has been available on-demand since 2013, but it hasn't been distributed systematically among police units.

4.2. Weaknesses/ challenges/ what's not working in the current way of working

According to the police, a weakness in the current system of narcotics control is that the whole process is time-consuming. For example, scheduling isotonitazene took too much time. They had information on the traffickers, but they couldn't act legally. After seizing the substance and identifying it in expertise, they should have returned it. Although it is not a frequent problem, they wish to be more effective than the current bureaucratic system allows. For example, a measure to impose a temporary ban on handling a substance, until further analysis is done.

In addition, the wait time for substance examinations is too long. The police's actions are always reactive based on that. There is a need for a more direct way of exchanging information with the PWUD that would help them identify whenever a new hazardous substance emerges on the market. Information exchange could be improved internationally also, especially with neighboring countries. All types of countries – drug producing, trafficking and consuming – need to work together to have an effect. This would prevent situations where a substance that is wreaking havoc in a country is unscheduled in a neighbouring country.

The state of rehabilitation programmes in the prison system was also pointed out as a challenge by LUNEST. Although officially programmes are provided, they aren't always carried out or are carried out ineffectively. Furthermore, it is known that people leaving prison have a higher risk of overdose, but in 2019 not a single naloxone kit was distributed by Tartu Prison. Prisoners can ask for a kit, but since this can imply an ongoing substance use problem, this is problematic for persons applying for an early release.

LUNEST was also critical towards drug testing by probation officers. Since the tests only show the so-called traditional substances, it can motivate people to use less known and possibly more dangerous substances, rather than to limit actual use. For example, isotonitazene cannot be identified yet by probation officers.

4.3. Needs: how to move forward/ how to become better prepared i.e. what is needed if we have to deal with a crisis in the future

There are no new methods planned by the police at the moment. They will continue current activities. Since the availability of SO-s is limited, there is no pressure to implement new approaches. Further emphasis will be put on monitoring social media and the darkweb. Even though SO distribution hasn't moved there yet, it has to be under constant scrutiny.

5. Conclusion

The prevalence of SO-s has been low in Estonia since 2018 and the police has a good overview of the SO market. However, there has not been a significant decrease in the number of active users, which means that the risk for the situation to quickly worsen is still high.

The current informal exchange of information is considered functioning, but its preparedness for an increase in SO prevalence is questionable. Targeting messages to specific groups is still a challenge.

The Estonian Forensic Science Institute considers themselves well prepared. However, the whole monitoring system is dependent on the data provided by them and their workload is high. This might create a bottleneck in the future.

The police find it difficult to be proactive with the current forensic expertise waiting times. There is a need for a more direct way of exchanging information with the users that would help them identify whenever a new hazardous substance emerges on the market. Interest in the LUNEST report shows that information provided by users is valued, but without additional anonymous drug checking possibilities evidence is often anecdotal.

Since 2016 narcotic drugs and psychotropic substances are scheduled by groups to control the spread of NPS, but the process of regulating substances outside groups is still time-consuming.

Tallinn EMS has a long and intensive experience with SO-s and considers their preparedness good. Calls regarding drug overdoses have seen a sharp decline as a result of limited availability of fentanils. Since late 90s the EMS protocols have been updated three times and a new code of conduct will be implemented this year.

As the field of addiction treatment has been a low national priority, the number of trained professionals in the field is insufficient. National curriculums for health care workers are not focused on drug addiction disorder and there are limited possibilities for continuing education in this field. In addition, there are no incentives in place to motivate specialists to work with this target group. This low interest is also reflected in poor motivation of psychiatric clinics to work with PWUD. Especially considering that there is acute deficit of psychiatrists in Estonia.

The State Agency of Medicines considers their SO preparedness high. Due to the strict regulations the nonmedical use of prescription opioids isn't considered problematic in Estonia. However, this has created the challenge of underprescribing, reducing the availability of medicines for patients who need them.

5.1. Recommendations

Naloxone is prescription drug and only doctors can conduct the training and distribute it. It would be beneficial to allow nurses and non-medical staff (harm reduction, shelters etc.) independently provide naloxone. Better access to naloxone for people released from prison is also important.

Despite the closure of the current national EWS, there is a need for a rapid information sharing / warning system (incl. digital interventions). It is crucial that it would involve all the relevant partners. This platform would need separate coordination.

User and NGO level data collection would be vital for this system but is limited without anonymous drug checking. Long waiting times for forensic expertise is also a challenge for the police. Research into appropriate drug checking models and possibilities (especially the legal framework) is needed.

There is a need to stay up to date on the newest trends involving social media, the dark web etc. This includes closely monitoring the ways drugs are distributed, while also using these technologies as a tool for harm reduction.

Reaching different user groups with relevant information requires finding out and establishing the appropriate channels. This should be done before the next crisis.

Emphasis must be placed on training health care workers (especially psychiatrists) and specialists from other fields, in the field of substance use disorders. Specialists currently working in the field need motivating to work with this target group.

The availability of services for PWUD needs to be improved (incl. case management across services) and adapted to SO and other NPS.

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Assessment of the Synthetic Opioid preparedness of Finland

Country Report Finland

1 A brief overview of the prevalence, trends, and incidents of synthetic opioids in Finland

The latest population survey on drug use and drug attitudes (Karjalainen et al. 2020) shows that during the past decades, drug use has increased at the population level. The main illicit drugs in Finland are cannabis, amphetamine, and buprenorphine. Non-medical use of prescription drugs is also common, especially among persons with problematic drug use. Prescription drugs are often used for intoxication purposes and to alleviate or enhance the effects of other intoxicants. The combined use of alcohol and drugs is a characteristic feature of substance use in Finland. In addition, substances such as amphetamine and pharmaceutical opioids are often used intravenously.

The most common misused opioid among the problem drug users in Finland is buprenorphine. Intravenous buprenorphine use is often boosted by other substances like benzodiazepines or pregabalin. Besides buprenorphine, the use of other pharmaceutical opioids—such as tramadol, fentanyl, and oxycodone—has increased. NPS are visible in the Finnish drug market, and some (such as alpha-PVP) have established their position among problem drug users. Yet, the overall use of NPS has remained low. The use of the main stimulant drugs (i.e., amphetamine, methamphetamine, ecstasy, and cocaine) is increasing. (Kriikku et al., 2018).

In Finland, the use of buprenorphine and other prescription opioids is more common than heroin. Heroin was replaced by buprenorphine in the Finnish drug market at the beginning of the 2000s. Heroin has not returned to the market and is almost nonexistent.

There are no signs of an increasing trend in the use of fentanyl from official sources in Finland. Fentanyls cause around ten fatal intoxications every year. However, the situation is being closely monitored, as the problem has been entirely different in neighboring countries (Sweden and Estonia). (Kriikku et al., 2018.)

The use of NPS has been relatively stable during the last years. However, there are PWUD who are replacing traditional substances with NPS or using NPS in addition to other drugs.

The buprenorphine in the illicit market is mainly smuggled from France and the Baltic countries and thus somewhat diverted from the treatment system. Finnish Customs and the Forensic toxicology unit of the Finnish Institute for Health and Welfare (THL) are working closely together to get a clear overall picture of what substances are entering Finland and which substances show up in deceased and living persons (drugs and driving, prisons, psychiatric clinics, etc.).

The number of fatal drug poisonings has more than doubled in the last 15 years. In 2019, there were 189 fatal drug poisonings in Finland. The number was nearly the same as in 2018 (188). There has been an alarming increase in fatal drug poisonings among young people in the last couple of years.

In 2019, buprenorphine was the most important substance detected in connection with 92 poisoning deaths. Other opioids also have a significant role in causing poisoning deaths in Finland (Figure 1). However, not all deaths caused by opioids are linked to the use of these substances for purposes of intoxication. Other accidental overdoses and suicides are also involved. In 2019, opioids were the most important substances detected in 80% of all drug poisonings. Buprenorphine almost never causes poisoning deaths on its own. A substance that depresses the central nervous system (such as benzodiazepine or pregabalin) or alcohol is always involved (Kriikku et al., 2018).

In addition to buprenorphine, the most important substances detected were the following opioids: methadone (19), oxycodone (31), tramadol (22), fentanyl (6), codeine (4), heroin/morphine (2), and dextromethorphan (2). In recent years, some deaths have resulted from the use of new synthetic opioids for purposes of intoxication. Although new opioids have not caused many poisoning deaths in Finland, vigilance is needed as dozens of people have died from them in our neighboring countries Sweden and Estonia in recent years.

The most concerning phenomenon linked to the use of the new drugs as intoxicants have been derivatives of fentanyl and other synthetic opioids. Of the new substances, there has been a special concern in Finland about U-47700, an opioid that was detected in connection with 11 deaths in 2016 and 2017. In most of the cases, the substance that was detected was also the cause of death. However, the substance seems to have disappeared recently from the Finnish market (Kriikku et al., 2019). It is typical of new substances being used as intoxicants to exist in a certain geographic area for a time (e.g., 1 or 2 years), after which it goes away, possibly to be replaced by a new substance.

Primary finding	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
buprenorphine	38	49	68	56	50	55	62	49	61	77	92
oxycodone	20	15	17	20	22	17	20	16	12	31	31
tramadol	35	47	39	40	40	31	20	20	26	34	22
methadone	20	15	19	5	11	11	8	6	10	16	19
codein	46	39	47	35	22	27	28	13	18	18	11
fentanyl	6	20	10	12	10	12	8	14	6	15	6
heroin	3	1	1	2	3	2	4	2	2	3	2
dextromethorphan					2						2
dextropropoxyphene				1	1	2		1	1		1
cyclopropylfentanyl										2	
fyranylfentanyl								1	1	1	
hydromorphone										1	
U-47700								9	2		
carfentanil								1	2		
morphine				2		1	2	2	1		
dyhydrocodein									1		
ethylmorphine				1			1				

Figure 2: Opioids in fatal drug poisonings in Finland 2009-2019 (THL 2020)

2. Monitoring systems

The existing methods of monitoring and data collection system for SO use and harms

Current information gathering by Finland:

Forensic toxicology, testing for intoxicants

- Information from the deceased, forensic autopsies: data from corpses is precise and systematic (compared to health care data), technical differences between countries emerge, especially with small amounts of substances and new compounds. For example, in Finland, a forensic postmortem is performed for all deaths related to illegal drugs. This means that the cause of death is known, as well as what possible intoxicants were detected in the deceased that might not be related to the cause of death.

- One of the challenges mentioned is: a quantity of drugs and a syringe are found on a deceased person. These could be utilized if it were possible. This is a matter that needs to be discussed with the police.
- Police and customs laboratories: one of the challenges is that commercial laboratories are joining in. It is important to establish the responsibilities and obligations of each.

Syringe residue analysis ○ Methods used in syringe drug residue analysis give detailed information on the prevalence and changes in drugs used intravenously, as well as mixed-use—the simultaneous use of several different substances.

Wastewater analysis ○ Gives independent information on the use of drugs in the area of a wastewater network almost in real-time. Population-level data from wastewater analysis is combined with research and registry data from other sources. This is how Finland gets a picture of the drug situation that is as reliable and multidimensional as possible. Combining the data also enables completely new types of approaches to evaluating matters that are difficult to measure in other ways, such as the monetary value of the drug trade or the amount of drugs consumed as opposed to the number of drug confiscations by law enforcement officials in Finland.

- By combining the trends in overall drug use observed in wastewater analysis with data on the degree of purity of drugs confiscated by law enforcement authorities, a short-term correlation is often observed. For example, at times when drugs on the market have a higher degree of purity, the amount of drugs used in the general population grows. In addition to representativeness, a key advantage of wastewater analysis is that it produces information on the drug situation almost in real time. This enables early identification of key changes occurring in the drug situation.
- Challenges: the drug content in wastewater is extremely small, and the use of buprenorphine, for example, cannot yet be reliably evaluated. The same applies to NPS. However, with the rapid development of equipment and analysis technology, studies will be easier to carry out in the future (Gunnar & Kankaanpää 2019).
- Wastewater analysis is a good indicator in detecting the use of drugs. However, it is impossible to separate the legal and illegal use of opioids in wastewater analysis.

The national focal point of the Reitox drug information network (operating under the EMCDDA) is hosted by THL. Its tasks include: ○ Collects and analyzes information on Finland's drug situation and shares the latest drug-related information both nationally and internationally

- Rapid Communication ○ Early Warning System (EWS) ○ Risk assessment
- A report on Finland's findings is sent to the EMCCDA once a year. One of the challenges mentioned by Finnish experts is that reporting once a year is not enough.

Seizures by Customs

Findings and seizures of substances that have not yet entered the market are primarily detected by the Finnish customs and the police. In addition to the seizures, NPS findings in forensic postmortem examinations

and driving under influence of drugs give a relatively good picture of what substances are currently in the markets.

Drug research

Surveys and high-risk drug use research project, substance use related cases in social and health services.

3. Health systems preparedness

Health systems preparedness in Finland is currently being developed, and emergency care is preparing for changes in the drug market by collecting emergency care reports from the most serious drug overdoses and by training and informing personnel about NPS and fentanyls in general and carfentanil in particular.

Emergency care is preparing for changes in the drug situation by collecting reports from emergency care on the most serious drug overdoses and by training and informing personnel about designer fentanyls in general and carfentanyl in particular. Emergency care works closely with the Poison Information Center.

> *"Generally speaking, identifying an opioid overdose and administering emergency treatment is already a part of the basic training of paramedics and emergency medical technicians. In connection with emergency care for opioid overdoses, all paramedic and rescue units (ambulances and fire units) are equipped with ambu bags and supplementary oxygen, and personnel knows how to use them. Treatment-level emergency care units, emergency care field management units, and of course medical units have naloxone, an antidote against opioid overdoses. In difficult opioid overdose epidemics, basic level emergency care units would probably be supplied with intranasal naloxone. Plans were initiated for this already at the time of a heroin epidemic at the turn of the millennium. Basic-level paramedics currently administer other medicines intranasally, so the threshold to introducing it would not be great."* (Interviewee No. 1)

The THN program is not available in Finland. Naloxone works best in overdose situations with the use of short-acting opioid agonists. The most commonly misused street opioid is buprenorphine, a long-acting opioid. There is no data on the doses and frequency of administration of naloxone or whether intranasal naloxone works at all with buprenorphine overdoses. However, the distribution of naloxone could be useful, e.g., in rural areas where it takes a long time for first aid to arrive (Rönkä & Niemelä, 2020).

Prescription opioids

The prevention of the illicit use of prescription opioids:

In Finland, prevention of the abuse of prescription opioids involves Current Care guidelines; electronic prescriptions and the ability of doctors writing prescriptions to see information in the prescription database, and the use of information in the prescription database for monitoring how pharmaceuticals are prescribed, and sending targeted, personal information letters to doctors. The letters contain targeted information on prescribing opioids and the possible problems that may be involved (Ahomäki et al., Impact of physiciantargeted letter on opioid prescribing, 2020).

Ahomäki et al. studied the effect of a physician-targeted nudge letter on opioid prescribing. In May 2017, the Social Insurance Institution of Finland sent a personal information letter to all physicians who had issued a prescription containing at least 100 tablets of a paracetamol-codeine combination to a new patient. The letter aimed to draw the physicians' attention to their prescribing practices and to decrease the size of the first codeine prescription. Using individual-level register data and a difference-in-differences strategy, Ahomäki et al. estimated that the letter decreased the average number of tablets purchased by new patients by 12.5%, and the probability of a first purchase being at least 100 tablets decreased by 6%. They also find that these effects were larger among consistent high prescribers. However, they did not find similar effects with other mild or strong opioids.

In addition, follow-up mechanisms for the delivery (and prescription) of pharmaceuticals are in use. If there is suspicion that a prescription has been forged, or that the doctor prescribing the medicine has been misled when giving the prescription, or that the pharmaceutical preparation is being abused, the prescription must not be filled before the supplier of the medicine has been in contact with the prescribing physician to ensure the authenticity of the prescription and the proper use of the pharmaceutical. If the prescribing physician says that the prescription must not be filled, or if the prescription is found to be a forgery, or if its authenticity cannot be verified, the electronic prescription must be locked or an indication of this must be made on the prescription form. If the prescribing physician cannot be reached, the pharmacy may supply the medicine in cases that it deems essential for the time that is needed for verification by the prescribing physician.

https://www.fimea.fi/documents/160140/764653/20644_Maarays_laakkeiden_toimittamisesta_SUOMI_2011-12-19.pdf

Challenge: the possibilities for an individual prescribing physician (awareness of the possibility of abuse, the situation of the patient, the right recommended treatment, the available types of pharmaceuticals and treatment options, etc.) to come to the best possible solution in each decision on treatment. Another possible challenge may be the reluctance of pharmacies to refuse to supply a medicine. Pharmacies have the right to refuse to supply a medicine if there is reason to suspect that it is being abused. *(Interviewee Nr.2)*

In addition, there is a guide: The use of opioids in the treatment of prolonged pain not caused by cancer – updated guidelines based on European recommendations.

The use of opioids in the treatment of prolonged pain not caused by cancer

4. Narcotics Control

Psychoactive substances banned from the consumer market are listed in the government decree on psychoactive substances banned from the consumer market (1130/2014). "Narcotics" are listed on the government decree on substances, preparations, and plants considered as narcotics (543/2008).

In Finland, the Finnish Medicines Agency Fimea, the National Institute of Health and Welfare, the Police, and the Customs assess substances and make proposals on substances to be controlled to the Ministry of Social Affairs and Health. The Ministry prepares the amendment(s) to the corresponding degree(s), and the final decision is made by the government.

If some substance on the list of psychoactive substances banned from the consumer market is later evaluated as harmful as substances on the list of narcotics or are banned at the EU or UN level, they are transferred to the narcotics decree.

Provisions for offenses concerning narcotics are laid down in Chapter 50 of the Penal Code (39/1889). The provisions for offenses concerning substances banned from the consumer market are laid down in Chapter 44 of the Penal Code – Offenses endangering health and safety. A generic classification for NPS is not possible in Finland.

Q: How could the new harmful substances that have not yet been classified as narcotics be brought under control faster than at present?

A: "Finland's national view, taking into account the Constitution and EU requirements, is that the classification process is already as fast as it can be. But of course, if we could hire three more people to look for substances and categorize them throughout the year, it would make things much faster. Now we classify about twice a year, and this process seems to have been enough to cover the emerging NPS. If there would be an acute need to classify something, that would be possible quite fast." (Interviewee Nr.3)

The Narcotics act allows banning new psychoactive substances and their positional isomers in two different ways after a national risk assessment. NPS may be banned as "psychoactive substances banned from the consumer market" or as "narcotics."

Why can we not ban and monitor NPS in Finland all at once?

Not all NPS drugs can be proactively monitored as a single large entity in Finland at the EU level or the UN level. However, in some EU countries, a concept called substance-group specific or generic classification is used nationally. This means that prohibited substances do not have to be specifically named by law but are prohibited if they are derived from a certain molecular structure as defined by law. In this case, variations of certain substances can be monitored without individually examining their adverse effects.

There is no generic classification model in place in Finland. Instead, the substances are assessed and added to the regulations individually. This policy is justified by the fact that citizens must be able to know in advance in a precise and clear manner which substance is banned and which is not. It must also be possible to know whether it is a drug or a psychoactive substance banned from the consumer market, especially because the Criminal Code of Finland has adopted different positions towards different substances.

The Finnish classification system is not without a fault, but it is clear-cut and fast. On the other hand, in the generic classification model, it is not possible to know without chemical expertise which substance is banned in the country and which one is not. The Finnish model is also capable of proactive monitoring because we can classify positional isomers for known substances, even if the isomer has not yet been detected in Finland or Europe. In Finland, a separate assessment of adverse effects and risks is carried out for each substance. Only after the evaluation will a decision be made on the classification of the substance. (THL 2021.)

5. Law enforcement preparedness

The total number of narcotics offenses has grown for the sixth year in a row. The number of detected narcotics offenses suggests that drug use is increasing. The domestic drug market has not seen any significant changes.

In Finland, drug-related crimes will be investigated with maximum efficiency. The control of drug-related crime is based on analyzed data and official measures. The Police, Customs, and the Border Guard collaborate to prevent the import of illicit drugs. Close international cooperation ensures the effective establishment of

criminal liability in cross-border drug crime. Crime control efforts will be directed at information networks as a facilitator for the distribution of narcotic drugs. *(Interviewee Nr.4*)

So far, neither fentanyls nor other synthetic opioids have played any significant role among police. A rough assessment suggests that the regular daily problem use of drugs in Finland applies to a specific circle of people, and that within this circle, certain well-established intoxicants (especially marijuana among cannabis products, amphetamine and ecstasy among synthetic drugs, and buprenorphine and benzodiazepines among pharmaceutical intoxicants) are constantly in high demand, and that is why these specific substances are smuggled into Finland. *(Interviewee Nr.4*)

Neither fentanyl nor the other synthetic opioids have been among these well-established substances. Drug users in Finland have been surprisingly good at recognizing among themselves (and partly based on public warnings by officials) that fentanyl, and especially its derivatives, are very dangerous substances because their "safe" doses are very small and therefore difficult to evaluate and because users do not necessarily know what substance they are actually using. *(Interviewee Nr.4*)

In contrast to the police, Finnish customs have found fentanyl derivatives in recent years, including butyrfentanyl, furanylfentanyl, methoxyacetylfentanyl, ocfentanil, and carfentanil. Nevertheless, the amounts have been relatively small, with furanylfentanyl being the most common. Both police and customs authorities have reported just a few cases of carfentanil. For example, in the autumn of 2017, the police confiscated some carfentanil cut with brown sugar, but the potency was very low. Fentanyls and their derivatives come to Finland mainly through the mail, ordered on the Internet. *(Interviewee Nr.4*)

So far, synthetic opioids and other substances that are most popular here have been easily available on the Internet with delivery by post, and that is why law enforcement officials have focused on postal customs. Criminal elements are drawn to the synthetic opioid trade by the potential for significant profits. As has already been established, the use and seizures of fentanyls have been very low in Finland compared with the rest of Europe and the United States, even though these substances would be very easy for criminal smuggling organizations to deliver to the Finnish market from Tallinn or St. Petersburg, which are only a couple of hours away. However, these substances have not been appeared on the Finnish market owing to a lack of any significant demand. However, this does not reduce the risk of individual cases, and the situation needs to be monitored closely, especially considering the complex ramifications of the ongoing pandemic. European trends in the use of intoxicants have often spread to Finland later than to other countries, and on a smaller scale. On the other hand, depending on the substance, the trends may never have reached Finland. This has been the case at least so far with synthetic opioids. *(Interviewee Nr.4*)

Of the countries near Finland, Estonia has seen fentanyl become one of the most popular intravenously used opioids in the country. The substance comes to Estonia mainly from Russia. In the Baltic countries and Russia, the use of fentanyl derivatives is common, resulting in a high rate of deaths from fentanyl overdoses in those countries. *(Interviewee Nr.4*)

In Finland's western neighboring country Sweden, seizures of fentanyl and its derivatives have been increasing, and deaths connected with its use have increased.

During 2019, police and customs seized around 793,680 tablets of narcotic pharmaceuticals (excluding Subutex®), the largest number in history. The use of narcotic pharmaceutical preparations containing benzodiazepines in particular is very popular among drug addicts in Finland. Due to the growth in online shopping, the number of narcotic medicine seizures made by customs is increasing, particularly in connection

with international mail control. The illegal import of narcotic medicines has exploded in the last six years as the importance of the Internet as a trading venue for illegal drugs has grown. *(Interviewee Nr.4*)

New psychoactive substances (NPS) from European marketplaces, ordered via the darknet and often originating from China, are still a problem, and their health risks are significant. NPS pose a growing threat and cause a risk of severe health problems or even death, particularly when used in combination with other substances. New psychoactive substances are detected regularly as older ones disappear from the market. NPS are identified in substantial numbers annually, although recently, the numbers of new substances have somewhat decreased in Finland. High potencies and a growing number of mixtures of various substances available on the market increase the health risks caused by NPS. These kinds of drugs are mostly acquired from online shops. *(Interviewee Nr.4*)

LAW ENFORCEMENT SECTOR AND PREPAREDNESS (focus on supply-side drug control)

As a member state of the European Union, Finland takes part in the implementation of the focal points of the EU Policy Cycle for organized and serious international crime. (EMPACT). Among the focal points of the activity are amphetamines and New Psychoactive Substances (NPS). The operative plans of the focal point include numerous actions and operations aimed at curbing problems related to illegal drugs. Synthetic opioids are also among the common European measures. At the national level, fighting the problem is a cooperative effort of the Finnish Police, Customs, and Border Guard with a shared strategy that includes surveillance and analysis activities. A focus has been placed on online discussions by setting up a special cybercrime center in the National Bureau of Investigation. The EU police agency Europol also has a special Cybercrime Center. *(Interviewee Nr. 5)*

A special aim of Police, Customs, and Border Guard activities is to intervene in cross-border and organized crime. Good collaboration has developed over the years into a form of cooperation that is valued nationally and internationally.

International cooperation works well through bodies such as the United Nations Office on Drugs and Crime (UNODC), Europol, and Interpol. Exchanging and analyzing information are cornerstones in the fight against the problem. Naturally, there are challenges stemming from the different kinds of systems in different countries and in international coordination as well as monitoring the darknet. In Finland, national coordination works excellently through the national drug coordination working group led by the Ministry of Social Affairs and Health. All relevant ministries and actors are represented in the group, where there is open discussion. Measures aimed at restricting supply and reducing demand are discussed together, and officials responsible for law enforcement also have an important role in prevention work and in measures aimed at reducing the harm caused by drugs, such as referral to treatment and replacement therapy. Finland does not have a big problem with fentanyls, but their dangers have been recognized, and preparations have been made through internal police guidelines on what to do if personally exposed or when meeting a person who has used fentanyl. *(Interviewee Nr. 5)*

The Police, Customs, and Finnish Border Guard (PTR) Cooperation

The PTR cooperation between the police, Customs, and the Finnish Border Guard aims to address crossborder crime and organized crime. The 2020–2023 strategy highlights the fight against cybercrime and disrupting the activities of international criminal groups seeking to enter Finland.

Cooperation in combating crime seeks to combine and benefit from the opportunities created by new technology. PTR cooperation effectively coordinates the activities of the authorities concerned. The cooperation is based on a shared view of situations and an analysis-based assessment of changes in the operating environment.

The cooperation between the PTR authorities is based on a common and proactive view of the operating environment, daily exchange of information, and consideration of each of the party's strengths. The goal of the PTR strategy is to steer the cooperation between the PTR authorities in a targeted and mutually agreed direction and to provide a basis for measuring the effectiveness of the cooperation. The PTR authorities' operating environment has undergone major changes in recent years, and this is likely to continue in the future.

Megatrends affecting the operating environment include urbanization, an aging population, the climate crisis, and rapid technological development. Working together in a flexible, fast, and efficient manner can increase safety as the operating environment changes.

The PTR authorities are stronger together than they are individually. Good cooperation has evolved over the years into a nationally and internationally respected form of collaboration. (Finnish Customs 2021.)

Customs and Border Protection preparedness

How is the law enforcement sector prepared for possible changes in the synthetic opioids market (including synthetic opioids sold on darknet markets)?

- *Strategically, we actively monitor the situation at the phenomenon level to keep ourselves aware of possible changes in the synthetic opioids markets. We are continuously evaluating our operating models and making improvements if we find it necessary.*
- *We are active members of various international forums fighting against this phenomenon.*
- *We have a separate national unit specialized in darknet investigations. (Interviewee Nr. 6)*

What is working, what is not working, what are some of the challenges or shortcomings in preparedness in the law enforcement sector?

- *Due to the good knowledge-sharing by various international and national cooperation partners (e.g., EMCDDA, Europol, UNODC, and the Finnish Medicines Agency), the awareness of synthetic opioids is at a satisfactory level.*
- *The cooperation, information, and knowledge-sharing at the national level between law enforcement authorities, forensic, and the customs laboratory works well.*
- *Occasionally problematic is the lack of resources. There is a lot of information available, and more could be done, but due to the limited resources, the actions need to be postponed.*
- *The suitability of information systems for analytical purposes could be better.*
- *International exchange of intelligence is occasionally too slow.* ○ *Differences in legislation on controlled drugs between various countries occasionally bring challenges. (Interviewee Nr. 6)*

- How could these challenges and shortcomings be addressed? ○ *Nationally and within the organization; prioritization of issues, directing staff and resources at the managerial level*
    - *The analytical needs have to be taken into account in a better way when developing new information systems*
    - *The importance of international cooperation cannot be underestimated, and therefore its development deserves attention. (Interviewee Nr. 6)*

- How can the cooperation organized between law enforcement and other relevant partners tackle the supply of synthetic opioids?
    - The cooperation between law enforcement and relevant partners is on a good level. There is a network of experts composed of representatives of law enforcement and other relevant organizations. *(Interviewee Nr. 6)*

- Needs: how to move forward / how to become better prepared?

    - *Our operations must be maintained and developed in order to meet the challenges of the future.*
    - *We need to be awake to notice the changes in time. The development of international cooperation plays an important role in this. (Interviewee Nr. 6)*

6. Early Warning Systems

Early Warning Systems (EWS) share information throughout Europe on NPS at as early a stage as possible.

When a new psychoactive substance is detected for the first time in customs enforcement, for example, the EU Member States inform each other through the EMCCDA and its Reitox network as well as the European Union Agency for Law Enforcement Cooperation (Europol) and its national units.

If Europol and the EMCDDA find that the information they are given requires the collection and analysis of more information, they will publish a joint report that is delivered to the European Council, the European Commission, and the European Medicines Agency (EMA).

The content of the report:

- The chemical and physical description of the substance and the name that the substance is known as.
- The frequency with which the substance is observed, the conditions, and the amounts.
- The ways and methods that the substance is produced.
- The role of organized crime in the manufacture and distribution of the substance.
- Indications of the social or health-related risks of the substance; typical features of the users.
- Is the substance now, or in the past, been monitored under the UN system?
- Is the substance already a target of control or measures at the national level in the EU Member States?
- The chemical precursors, the established or expected magnitude and method of use, or possible new methods of use.

The European Medicines Agency examines sales licenses.
The European Medicines Agency delivers information to Europol and the EMCDDA on whether or not a new psychoactive substance has been given a sales license in the EU or its member states.

- If a sales license is being sought or if a sales license that has been granted has been canceled. The risk assessment evaluates the risks related to the substance from many angles.

Based on the joint report, the European Council can ask for a risk assessment of a substance, in which the various risks connected with the substance are studied.

- health risks
- social risks
- risks connected with the use, manufacture, and distribution
- the involvement of organized crime
- possible consequences of control measures

The availability of comparative material is important in the identification of the substance.
With a new synthetic substance on which only limited scientific research is available, it is important to get material so that comparisons can be made.

Forensic and toxicological laboratories need comparative material for identification, either of a substance that has already been confiscated or a similar substance.
There is agreement at the EU level on measures in which samples of confiscated substances are exchanged among different countries. (THL 2021.)

The Finnish National Focal Point of the Reitox drug information network operates under the European Monitoring Center for Drugs and Drug Addiction. It is hosted by THL (Finnish Institute for Health and Welfare). Focal Point collects and analyzes information on Finland's drug situation and shares the latest information both nationally and internationally. The international EWS system has not been developed to be rapid. In Finland, the main source of information regarding NPS is the Reitox network and the EWS network.

Important sources of information regarding NPS are substance abuse services, low-threshold service centers for PWUD, outreach work, and housing units. It is important that experts get information on NPS from the street and vice versa.

The role of communications needs to be more rapid. One of the challenges is how to arrange a rapid flow of information network: exchanging information and a rapid flow of information are important, and the network with a fast flow of information should be comprehensive. Many European countries have shortcomings and room for improvement in the rapid flow of information. For this reason, more detailed planning is needed for coordinating, implementing, and reporting on data. The way that the information is made public should also be planned.

It would also be a good idea to utilize Internet message boards, for example, as sources and in the dissemination of information. It is very important to be present on all channels. It is of maximum importance to disseminate information beyond the EMCCDA. Reporting once a year is not enough.

Nopsa network

Nopsa is a Finnish professional network for rapid drug information. Nopsa network members meet regularly to exchange information and discuss current drug findings. Network shares rapid information on new drug threats and changes in the drug market. In the network, professionals discuss recent phenomena related to drug use. The network includes professionals, authorities, and peers. The network's activities are focused on the Helsinki metropolitan area.

The A-Clinic Foundation's communication coordinates the Nopsa network with the "Verkko-Vinkki" (OnlineAdvice and harm reduction in the anonymous Tor network project). In addition to regular appointments, the contact is kept on the mailing list of over 400 members.

> *" The network hopes for a faster exchange of information from laboratories as well as drugchecking services. Finland could take the example of France (Giaurdon & Bello 2007), for example, where the NGOs are connected to the state's monitoring system." (Interviewee Nr. 7)*

The drug-checking service could give valuable information on new substances on the market in Finland. At present, current information on the drug situation can be found mainly in confiscation statistics of police and customs authorities and wastewater analysis. If samples were available directly from the user, identifying new substances and especially dangerous substances could be faster. The faster that new substances and exceptionally dangerous batches of substances are identified, the easier it is to respond to the harm that they cause. (A-Clinic Foundation 2021.)

Substance identification integrated with intoxicant services would make it possible to:

- reduce harm and risks related to drug use,
- establish contact with people using drugs at an earlier stage than is now the case,
- provide information to health authorities on the arrival of an exceptionally dangerous batch or new substance on the market, possibly before any of the substance is confiscated. (A-Clinic Foundation 2021.)

5. Conclusions

Finland has a relatively good situation regarding readiness, and Finland is considered a "model country" in preparedness. Despite this fact, the number of drug-related deaths in Finland is among Europe's highest. Because potent SOs are on the rise in Europe and can cause serious harm, including nonfatal and fatal injuries, preparedness systems for SOs need to be strengthened to prepare for possible changes in the drug market.

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Country Report Germany

Strengthening Synthetic Opioids health systems' preparedness to respond to the potential increases in prevalence and use of Synthetic Opioids (SO-PREP) - WP 3 country report: systematic review of the literature evaluating prescription

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1. Introduction

Over the past few years there has been a rapid rise in the use of new psychoactive substances (NPS) in the world [1]. Similarly, in Europe NPS have become one of the most important drug-related issues in the recent years. The EMCDDA European Drug Report of 2020, reported that by the end of 2019 over 790 NPS were being monitored by the EMCDDA [2]. Peaked in 2014 with almost 100 NPS, the number of new NPS has stabilized at around 50 NPS a year in recent years [2]. A bundle of reasons including NPS control strategies in Europe, as well as policy changes in the countries of origin to restrict production may partly explain the observed decrease in NPS use in Europe; however, a large number of NPS is still available on the drug market in Europe [3].

Data on epidemiology of NPS use and harms in Germany are scarce; however, the existing evidence shows that different types of NPS are available on the drug market and are being used in Germany. A recentlypublished study evaluating 295 drug users seeking treatment in eight facilities revealed that almost one third of the participants had ever used synthetic cannabimimetics, while the main self-reported reason for using NPS was that “NPS were not detected by drug testing in prisons or drug treatment facilities” [4]. In addition, the 2015 Epidemiological Survey of Substance Abuse in six federal states of Germany found the lifetime prevalence of NPS ranged from 2.2% in Bavaria to 3.9% in Hamburg [5]. Germany has been facing many challenges on legislation of NPS entering its drug market in the recent years [6].

Synthetic opioids (SOs) are one of the NPS subcategories manufactured in laboratories. Fentanyl is one of the best-known synthetic opioids that is up to 100 folds more potent than morphine [7]. Due to the high potency of fentanyl and other synthetic opioids, they are responsible for a large number of overdoses and mortalities around the world. In the US, for instance, over 80,000 deaths due to drug overdose occurred in the 12-months ending in May 2020, of which approximately 40% were estimated to be associated with SOs
[8].

Few studies have evaluated SO use and harms in Germany, while the available information is mostly dated. Published in 2019, Kraus and colleagues estimated the number of people who are addicted to opioids (not specifically synthetic opioids) in Germany. According to their estimation in 2016 almost 170,000 German people were addicted to opioids, where opioid addiction per 1,000 general population ranged between 0.1 in Brandenburg and 5.5 in Bremen [9]. A systematic review of the literature evaluating prescription opioid in Germany found fentanyl was the most prescribed strong opioid in outpatient settings in this country, although it was not the first choice for patients with chronic pain [10]. The aforementioned review also suggested that the majority of prescription opioids in Germany was prescribed for non-cancer patients [10].

The European research project SO-PREP aims to contribute to the enhancement of SO preparedness of European countries to effectively monitor and respond to increases in SO prevalence and incidents (for more information see: https://so-prep-project.eu). In line with the aim and objectives of the Work Package 3 (WP3) of the SO-PREP, the current study was designed and conducted to evaluate the current methods of detection of SOs in Germany and early warning system at national and local levels, and preparedness of Germany to face a potential SO crisis.

2. Methods

In January 2021 we selected six experts working in the field of NPS in Germany and invited them to the interview, of them four accepted our invitation. The interviewees were either part of- or in close contact with the drug monitoring agencies in Germany. They were also in close collaboration with police department, hospital emergency units, forensic medicine institutes and the other organizations in contact with drugs, in specific NPS in Germany. The participants were affiliated to the following organizations:

- Institut für Therapieforschung München/German Monitoring Center for Drugs and Drug Addiction (the Reitox focal point in Germany)

- Condrobs München

- Legal High Inhaltsstoffe

- Institute of Addiction Research; Frankfurt University of Applied Sciences

In the present study we used the interview guides prepared by the SO-PREP partners in Finland as the main data collection tool. The interview guides contain questions on four main themes including 1) monitoring system, data collection and detection; 2) prevention and health system preparedness including illicit use of prescription opioids; 3) law enforcement sector and preparedness including narcotic control; and 4) local early warning system in Germany.

All interviews were conducted in February 2021 and each interview lasted between 35 and 50 minutes. Prior to starting the interviews, the interviewees were informed about the aims and objectives of the SO-PREP and the interviews as a part of the WP3. Permission was granted from all participants to record their voices for the purpose of research, while we assured them that the interviews would be anonymous and their personal information would remain confidential.

3. Findings

The participants were asked about the history and current status of SO use and harms in Germany. Emerged from the interviews, between 2006 and 2012 there was a rapid increase in the use and overdose mortality involving fentanyl in Bavaria. Although Munich was the epicenter of that outbreak, some other cities such as Stuttgart and Tübingen were also affected at that time. According to the interviewees SOs are currently no major public health threat in Germany. In this regard one of the participants stated that:

> *"I cross fingers nothing much has happened since the early awareness that fentanyl is in the country, and some anecdotes in the beginning that drug users are very keen on the rubbish of hospitals in order to get plasters for pain relief containing fentanyl. We heard that in the cities like Munich, but until now it [synthetic opioids] remains a remote topic. We did hear from Prof. Dr. [name of the person redacted] in [name of the city redacted], who's doing substance analysis in some consumption rules in Germany. We hear that fentanyl here and there plays a role, but fortunately not a big role."*
>
> (Interviewee Nr.4)

1. Monitoring and data collection system

The participants were asked about the existing methods of monitoring and data collection system for SO use and harms in Germany. According to the participants, although limited number of forensic labs and the police in different states have access to data on SOs, in general there is no systematic method for monitoring SO use and harms in Germany. In this regard one of the participants stated that:

> "*Since decades we're asking for systematic reporting from forensic labs. We do have well established system of autopsy or toxicological analysis of any kind of substances that do work more or less properly, but in most of the cases it is the budget question. As you may know for drug-related deaths we do not even have reliable number, which is frankly speaking scandal, being citizen of one of the richest countries in the world and people do not even care about what people die from. It's quite different from ten years ago. To my knowledge it's pretty easy to systematically look for, for example, fentanyl that remains [in the body].*"
>
> (Interviewee Nr.1)

Numerous factors were discussed as potential reasons for the lack of systematic monitoring and evaluation of NPS including SO use and harms in Germany. Lack of resources and financial support was one of the frequently-discussed reasons. Among all the themes discussed, one of the participants pointed out lack of willingness of a lab director to share data on drug-related mortality with the other scientists and policy makers, since she was planning to publish the results in a peer-reviewed journal:

> *"She was the first one having data on fentanyl, I think it was eight or nine years ago. She carried out analysis and found considerable numbers [of death due to fentanyl], but we approached her and asked her for more information to report on it, and beyond all political issues there was also response: "well we did carry out the analysis, we do have some numbers, but we should be the first one who reports that first in a scientific context"".*
>
> (Interviewee Nr.1)

Lack of national action plans due to the federal political structure of Germany, as well as lack of collaboration between different beneficiaries were mentioned as potential reasons explaining poor SO monitoring and data collection system in Germany. To address this issue one of the participants suggested that:

> *"I think there should be more exchange [of information] between the drug service centers and the police. Of course the police get drug from the street and somehow this drug goes to the research but we don't know what they will find. We don't get information from them. This should be getting better."*
>
> (Interviewee Nr.3)

2. Prevention and health system preparedness

According to the respondents the existing prevention strategies to control SO use and harms in Germany seems not to be satisfactory. In other words, it seems that the current health system of Germany is not prepared to timely respond to any potential SO epidemic in this country. "Deutsche Aidshilfe" was reported to be the only organization producing educational material and distributing knowledge on HIV/AIDS-related risk factors including drugs, that includes also synthetic opioids, in Germany. Educational materials such as

posters and brochures are freely available on the Aidshilfe website and accessible for everyone (e.g. fentanyl brochure is available from https://www.aidshilfe.de/shop/fentanyl). However, regarding the SOs the respondents were not aware of any systematic methods of knowledge distribution among the most at-risk populations including young people, drug users within the community, and drug users in sub-populations e.g. prisons.

A strong early warning system with a wide range of beneficiaries was recommended as one of the most effective methods to detect SOs and to mitigate their harms. According to the respondents a systematic monitoring systems requires a committed group of players collaborating closely, which is currently missing in Germany. In this regard one of the participants quoted as follows:

> *"We really need a good and fast early warning system. At the moment there are new decisions about that, but I really think we need to establish such a system with different players in that: police, social workers and etc.…"*
>
> (Interviewee Nr.2)

Monitoring street drugs through 'drug checking' or the other forms of laboratory analysis of drugs were recommended by the respondents as an effective method to track any changes in the chemical structure of drugs, and to mitigate the possible risk of new SOs in Germany. One of the interviewees mentioned the benefits of a drug checking system that was implemented for two years as a part of a research project in Germany:

> *"We need drug checking not only the drug users but also for the early warning system. It was part of a research project called "Drusec". During these two years the drug users could bring us some drugs, we sent them to Freiburg (for analysis), and in a couple of weeks we got the information back. I think that was good for the users and also good for us. I think that should be a normal part of drug monitoring. Now these two years is over and we don't have it anymore."*
>
> (Interviewee Nr.3)

In addition to scaling up a systematic method of data collection, increasing awareness towards SOs and the other NPS was another suggestion to prevent the use and harms of these drugs in Germany. In this regard one of the participants quoted as follows:

> *"The suggestion is to stay alert, to sensitize drug users from the purchase of drugs of unknown purity or even unknown dealer. We have to speak more frankly about all the purchase systems. I would suggest as well [to change] the way we observe fentanyl spread in Germany; to make more use of analytical searches for fentanyl and the other synthetic drugs that is [currently] being done on a selfinitiative basis in Germany."*
>
> (Interviewee Nr.4)

Suggested by the interviewees maximizing collaboration between different sectors, expanding the heroinassisted treatment, distributing naloxone, fentanyl straps and the other kind of rapid tests, as well as educating police, healthcare staff members, and parents were the other interventions that could prevent use and harms of SOs in Germany.

Prescription opioids

Despite the existing weaknesses in the early warning system and prevention interventions Germany has a strong system for monitoring prescription opioids. There is a multi-level auditing system monitoring prescribed opioids both at the place of prescription (e.g. praxis and hospitals), and the place of distribution (e.g. pharmacies). The doctors have also access to the data on previous prescription time of patients in order to avoid double prescription, in specific in different cities. Apart from that, physicians in Germany need to attend a 60 hours course on substance use and addiction medicine to be allowed to prescribe opioids for patients. Currently there are less than 3,000 doctors who are allowed to prescribe opioids in Germany. One of the participants explained this process in detail:

> *"This 60 hours training contains not only information for opioids, but also for alcohol, nicotine, or any kind of addiction medicine. And this 60 hours training has also been taken over as a format to train for instance nurses and social workers dealing with psychosocial care for people in substitution treatment. I myself am part of this training. That is one level of quality assurance. Another level of control is being taken by the "Kassenärztlichen Vereinigungen" (name of an organization): doctors can be checked in a quarter of a year in order to get the prescription system controlled. "* (Interviewee Nr.4)

3. Law enforcement

From the respondents' point of view legislation of the NPS in Germany is a long bureaucratic process that jeopardizes harm-reduction interventions in this country. The police staff members need special training on NPS and specially SOs. As mentioned previously, each state in Germany has its own rule and regulations regarding drugs and drug control. Besides, Germany is a member of the "Schengen" agreement with no border control within the Schengen area. However, there are special drug search systems in places where passengers or goods enter into the country (e.g. airports, harbors, etc.). Such investigations cover all kind of drugs rather than only NPS or SOs, however, not all checking points are equipped with modern equipment.
In this regard one of the interviewees mentioned that:

> *"…for instance in the harbor of Hamburg they have huge container control that is a sort of radar system. They are checked through this system and from time to time we read in the newspapers that new shipments of drugs have been discovered. The biggest found ever was detected last summer and it was more than 1.7 tons of cocaine. The other harbor "Bremen harbor" is the second biggest harbor in Germany has no radar device to check the container. And we are geographically in the Schengen area. Schengen has no direct boarder control anymore, but the border control police is allowed to enter to get into the country I think 50 or 60 kilometers. If they have got suspicious they will follow the car crossing the border and stop that to control the trunk."*
>
> (Interviewee Nr.4)

Legalization was one of the options to control the use and harms of SOs in Germany. suggested by the interviewees. In this regard one of the participants stated that:

> *"I am a member of the [name of the organization redacted]. I always think we have to think about legalization options, for instance to better give away heroin like methadone program. I think putting people in prison or jail does not really work."*

(Interviewee Nr.2)

4. Local early warning system

The EMCDDA has a national focal point in Germany, which is responsible for monitoring NPS; however, from the interviewees' point of view the current monitoring system at both national and local levels in Germany is far away from an effective monitoring system. Regarding the national early warning system one of the participants stated that:

> *"I wouldn't call it an early warning system. I was surprised myself. The IFT in Munich where the Reitox focal point is based in, they are collecting data, and the way it goes is that they are requiring data from all institutions (police, border control, science and research) and persons (stakeholder, scientists etc.) involved. And of course the "German Statistics on Drug Services" - Deutsche Suchthilfestatistik is a comprehensive program which stores data only on treatment and first prioritized drug. On top of that there are some additional studies financed by the ministry of health. But the task of the Reitox focal point is to gather all these data together and to operationalize into an annual report.."*
>
> (Interviewee Nr.1)

Another topic discussed was the availability and function of the local early warning system in Germany. According to one of the participants at the time of fentanyl outbreak in Bavaria there were some meetings containing representatives from the police, hospitals, policy makers, social workers and the other beneficiaries; however, these meetings did not continue after controlling the outbreak. At the moment there are some sporadic occasions e.g. meetings with people from different sectors (including police, social workers, etc.) in few cities; however, according to one of the interviewees NPS and drug use in general is not discussed frequently as there are many other topics to be discussed in such meetings:

> *"…this is always very arbitrary. It is not systematic way of collaborating police with social workers or any other drug agencies and drug services or so. It's nothing! It's arbitrary, isolated and anecdotally, and I think this is the vocabulary we have to apply when describing the situation in Germany. There is nothing systematic or let's say structurally-implemented or so. No way!"* (Interviewee Nr.4)

4. Conclusions

According to the participants there is no systematic method of monitoring and data collection on SO use and harms in Germany. The existing organization having data on this issue (e.g. police and forensic labs) have no intention to share their own data.

There are also numerous shortcomings in the prevention strategies in Germany. Although the "Deutsche AIDShilfe" is actively involved in knowledge dissemination on SOs in Germany, it seems that there is no systematic program to raise awareness among the most at-risk populations including young people and those who inject drugs in Germany. On the other side, there is a strong monitoring system to track prescription opioids in Germany. The doctors need to attend specific educational courses on addiction to be able to

prescribe opioids. Besides, the opioid prescription process is monitored by the governmental organizations on a regular basis, which minimizes the risk of double prescription and misuse.

Due to the federal political structure there is no national rules, regulations, or action plans to mitigate the use and harms of SOs in Germany, while there is no political will at the state level as well. Border control is done through modern equipment in only few areas e.g. Hamburg harbor, while the control at the land borders and airports follows the same pattern as in the other members of the Schengen agreement. The aforementioned methods of border control in Germany are applied for all types of drugs, rather than only NPS or SOs.

The early warning systems at the national and local levels in Germany need a major revision. The interviewees suggested some interventions to strengthen the early warning system and consequently to mitigate the use and harms of SOs in Germany. These activities include: to maximizing collaboration between different sectors, to expanding the heroin-assisted treatment, to distributing naloxone, fentanyl straps and the other kind of rapid tests, as well as educating the police, parents and healthcare staff members.

The participants of our study believed that SOs are not a major health threat at this moment in Germany; however, the existing shortcomings in the monitoring, data collection, and early warning systems in Germany leaves no doubt that the healthcare system of this country would not be ready to timely respond to a potential synthetic opioid crisis.

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Country Report Netherlands

Assessment of the Synthetic Opioid preparedness of the Netherlands:

Description of the situation, responses and recommendations

Introduction

In Europe, highly potent synthetic opioids (SO) and related overdoses are a growing public health and safety threat. SO-PREP is a two-year European project focusing on strengthening health systems' preparedness to timely and effectively monitor and respond to increases in the prevalence, use and harms of SO.

This report describes the situation in the Netherlands regarding the use and misuse of SO and the available monitoring and response systems. It is part of a wider research activity in SO-PREP on how countries (involved in the project) are prepared for potential increases in SO use and incidents. The present report will describe the Dutch government's current strategies for monitoring and responding to the SO situation in the country. It will describe the overall systems to monitor and address licit and illicit opioid use and availability and it will describe the specific SO measures that are being taken.

Methodology

The research in the Netherlands was conducted by interviewing a range of key experts on the various topics as defined in the SO-PREP project, namely monitoring systems, health systems, and law enforcement systems.

The term 'synthetic opioids' refers to any prescription and non-prescription (semi-) synthetic opioids, such as fentanyl and fentanyl-analogues, tramadol, U-4770.

This research looked at both the legal and illegal settings, including the illegal 'black market' of SO, diverted prescription opioids used in the non-medical setting and for non-therapeutic purposes, and the current situation with prescription opioids and how professionals are trying to prevent the development of a new generation of opioid users.

Interviews were conducted with the following key experts:

- Daan van der Gouwe, Trimbos Institute, senior researcher at the Netherlands Focal Point to the EMCDDA Reitox network, ○ Laura Smit Rigter, Trimbos-institute, national coordinator of the Drugs Information and Monitoring System (DIMS), ○ Anke Lambooij, pharmacist at the Institute for the Safe Use of Medicines' and coordinator of the Taskforce Opioids ○ Vincent van Beest, policy advisor, Ministry of Justice and Security
- Marcel Bouvy, pharmacist and researcher, coordinator of the research project TAPTOE ○ Sara Woods, researcher, Foundation Mainline, harm reduction agency with outreach activities ○ Sebastiaan Venhuizen, pharmacist, National Institute for Public Health and Environment **Findings**

The following chapter will describe the findings on the SO situation and on the government's drug monitoring and warning systems in the Netherlands, as well as specific actions that have been undertaken to address the SO situation in the country.

3.1 Current situation

3.1.1 Prescription and use of prescription opioids

In recent years, there has been a rising concern about SOs in the Netherlands. Although there are no signals that the use of illicit SO is highly prevalent in the Netherlands and no major consumption potential is reported, the over-prescription and possible diversion of pain medication is of great concern. The Netherlands had been witnessing a steady increase in prescription opioids over the past 10 years, similar to many other EU countries (Stichting Farmaceutische Kengetallen, SFK).

The overview of the current situation regarding prescription and use of SO for medical purposes is incomplete, in that it lacks insight into the population of people who developed a dependency on these medications. There are several indications that current SO prescription practices are leading to substantial groups of (ex) prescription users who may have SO dependency problems. "*Opiates were stored in a separate box, locked with a special key. Nowadays they are stored in a big drawer, which is always open*," according to pharmacist in recalling the situation 30 years ago in one of our interviews.

Data on registered prescriptions show considerable increases in painkiller prescription, in particular Oxycodon, which increased fivefold within a decade (from 93,000 patients in 2008 to 485,000 patients in 2018). Patients who are prescribed fentanyl nearly doubled in that period (from 65,000 to 111,000 patients).

International research (e.g. Brummett CM et al. 2017) indicates that an estimated 5-10% of all patients on SO have increased vulnerability for addiction. For the Netherlands this would be 5,000 – 10,000 people.

These 'loose' prescription practices were also partly promoted by international discussions on the relevance of pain management and access to effective pain control as an essential human rights. This discussion has gained ground over the last 15 years and was also supported by pharmaceutical initiatives to promote sales of pain medications. Access to effective pain medication is also topic of interest in the Netherlands, several websites focus on pain medication and some of them are linked to pharmaceutical support (for instance www.changpain.nl is explicitly sponsored by the pharmaceutical company Grünenthal) but there are no signals of a situation like in the US where certain companies systematically actively misled and corrupted clinicians to prescribe their so-called 'non addictive' painkillers.

3.1.2 Diversion market and misuse

There is very limited information on the scale of diversion of opioid medications by patients (the 'grey market'). There are incidental signals of organized diversion due to misconduct. According to the Inspection Health Care and Youth there have been incidental cases of theft and fraud in the recent past (e.g. 1 GP in The Hague, 1 pharmacist in Utrecht), but there larger concerns of more systematic international trade of stolen packages of medications and of counterfeit packages with barcodes.

3.1.3 Risks and incidents

In ten years' time the number of information requests at the national intoxication helpline increased tenfold: from 43 in 2008 to 424 information requests in 2018 (Kan et al., 2019). The Municipal Health Service in Amsterdam reported 7 fatal SO overdoses in the years between 2013-2017 which were related to SO.

A survey among five institutes for addiction care showed that the number of clients having a problem with strong painkillers increased in the past six years from 92 to 292 clients (Kuiper, 2019). One treatment agency in the south of the Netherlands reports regular new SO clients . "*Once every week a new person. Often young and without previous heroin experience.*")

3.1.4 SO available on the Illegal market

Another source of SO is the illegal (online) market, where illegal substances are being offered and can be bought. Little is known on the non-medical ('recreational') use of fentanyl and fentanyl analogues, but the use of these substances seems limited in the Netherlands.

One point of concern is the increase of fentanyl transit and possible production in the Netherlands. In 2020, two incidents were reported and made the news: at one location the police found 2000 liter fentanyl precursor and at another location 1 kilo of ready-made fentanyl was found. There is serious concern that this may be the beginning of a trend of domestic SO production. One of the interviewees stated the following: "*Fentanyl is easy to produce. Simple raw material at modest prices, simple process, quickly prepared. A student pharmacology can prepare this*."

At the moment, special attention is also paid to a number of particular SO substances: isotonitazene, U variants (like U-47700, MT-45) and Tramadol.

There are no reports from the MSM scene on SO use; consumers are more likely expected to be among people who are familiar with opioids (e.g. from drug treatment or from prescription medication).

3.2 Monitoring systems

The Dutch Early Warning System (EWS) is closely linked with the EMCDDA EWS. It is part of the EMCDDA system that links national monitoring, European risk assessment, generic European control measures and national legal follow-up. The EMCDDA has developed a common terminology, guidelines and reporting instruments in order to harmonise the data collection across the European network. The national EWS receives annual updates for national follow-up.

The Dutch EWS system has three distinct elements:

a. Monitoring
b. Risk assessments
c. Control measures

3.2.1 Monitoring

The system has gradually developed in the Netherlands over the last 25 years. It is an elaborate and comprehensive system with input from various sources, such as law enforcement agencies (e.g. customs, police), the healthcare system, and consumers. In particular the consumer input (either provided by user panels like in the 'Antenne' research or from the national Drug Information and Monitoring System (DIMS)) is a special asset for the capacity to monitor and understand certain trends and patterns of drugs availability and consumption.

3.2.2 Drug Information and Monitor System

Drugs Information and Monitoring System (DIMS) is a national network of 31 locations across the Netherlands where substances can be submitted for drug checking. The aim is to gain insight into the market for illegal drugs and to identify and warn about health risks. DIMS is funded by the Ministry of Health and local treatment agencies and it is coordinated by the Trimbos-institute. It is one of the oldest drug testing systems worldwide. DIMS provides a combination of consumer service with the opportunity to gather data on the provided substances and to monitor drugs availability and consumer trends. In 2018, 13,540 visitors supplied 12,634 samples for testing. Staff of DIMS also monitors the online markets (both Clearnet and darkweb) on the sale of substances and other consumer trends. One weakness of the drug checking service is that it is not fully known what groups of people who use drugs make use of these services. In general, it seems that mostly recreational users make use of the services, while marginalized drug users do not. But further details on specific user groups are unknown.

3.2.3 Meldpunt Nieuwe Drugs (MND)

MND is an information point that collects information on new substances. Professionals can notify MDN if they find a new substances or suspect that they found a new substance. It was established in 2012 to target the growing number of NPS at that time. According to MND there are increasing signals of the mixing of markets of medical and non-medical substances and the use of (counterfeit) medications for recreational purposes.

3.2.4 Monitor Drug Incidenten (MDI)

MDI is an information system that was established in 2009 that monitors the nature and extent of drug related incidents. Data are been provided by ambulance services, emergency services, hospitals and forensic doctors in incidents in 8 regions in the Netherlands. Data on intoxications with synthetic opioids are been

collected since 2019. According to MDI incidents with opioid painkillers are currently mainly coming from ambulance services who report a 7% of the (non-alcohol related) incidents related to SO and in many cases related to suicide attempt.

3.2.5 Wastewater analysis

Wastewater analysis is a scientific method to monitor real-time data on geographical and trends in illicit drug consumption. Wastewater analysis are conducted frequently in the Netherlands. There is a yearly EMCDDA analysis, which currently includes 3 cities in the Netherland. Several drugs are analysed, but SO are currently not part of the list of researched drugs. Dutch Wastewater Management Agency (KWR) is the agency that is responsible for the waste water disposal. They are part of a recent EU-supported project EUSEME which aims to do qualitative and quantitative research on NPS and in particular synthetic and prescription opioids.

The Dutch Ministry of Health recently announced a plan to intensify ongoing surveillance of COVID-19. Sixhundred samples are collected a week and stored for a period of 5-10 years. If wanted, the samples could also be analyzed for SOs.

3.2.6 Risk assessment

The Netherlands has a dedicated national committee commissioned to assess the risks of new substances, mixtures, applications and trends, and to provide independent and swift recommendations to the Ministry of Health (Coördinatiepunt Assessment en Monitoring nieuwe drugs, CAM). CAM was established in 2000 and is formally mandated by the Ministry of Health. It is a multidisciplinary group of experts from various domains such as research, health care and narcotic control. The committee is able to commission targeted lab research at the National Poison Center (NVIC). CAM meets 3 times a year, or more frequently if specific concerns justify a swift assessment. All substances are assessed on 16 criteria in 4 domains: public health, individual health, public order and criminality. According to the interviewed experts the presence of an advisory committee as CAM is highly relevant and important. CAM's existence and work is a good example of the Dutch policy culture that aims to be based on scientific evidence.

3.2.7 Red Alert

Part of the monitoring and early warning system in the Netherlands is the possibility to announce a public warning, the so called 'Red Alert'. Red Alert is national or regional warning if there are signs of unusual harms of risks caused by specific drugs. The warning starts a procedure of rapidly performed identification and warnings, including an app-based consumer notification. The Red Alert system operates under responsibility of the Ministry of Health, the procedures are protocolized.

There are three situations in the Netherlands that can initiate a Red Alert:

1. When drugs with a serious health risk have been offered and identified at one of the drug checking facilities.
2. When the police or National Forensic Institute (NFI) find hazardous drugs.
3. When local medical authorities report serious incidents with drugs.

Risk analysis of the substance is performed based on chemical analysis and user information, but also on literature research and expert consultation from other sources such as the police or NFI, the National Poisons

Information Centre (NVIC) and the Monitor Drug-related Incidents (MDI). Once all relevant information is collected, the National Core Team Red Alert assesses the situation. This core team consists of representatives of the Ministry of Health, the Health care Inspectorate and the DIMS- bureau. The National Core Team Red Alert then has several options, depending on the severity and scope of the situation:

1. An internal release, in which only the participants of the DIMS network and the medical authorities that are part of the MDI are informed.
2. A regional or local warning, in which all listed local authorities are also informed by the coordinators of the DIMS network.
3. A national warning, which communicates its warning through a wide variety of channels such as press releases and flyers.

The Ministry decides when a Red Alert starts and ends.

3.3 Targeted Government health SO responses

Around 2015-2016 the first signals of the alarming SO situation in North America, with massive increases in SO use, incidents and overdoses, raised attention among many Dutch key stakeholders. The Coordinating Risk Assessment Committee (CAM) made a risk assessment on fentanyl and analogues in 2018. The assessment stated increased concerns in the Netherlands on increased availability, trade transactions and also a (modest) rise in SO intoxications also due to limited insight in consumers population, pattern and motives.

3.3.1 Opioid Taskforce

In 2019, a coordinated government action started activities to address the high prevalence of SO prescriptions and possible diversion and misuse, which can lead to chronic or problematic opioid use.

Following the concerns on SO medication and possible diversion issues, which were raised at an expert meeting in 2018, the Minister of Health, Welfare and Sport commissioned a national Task Force to address the situation around the overprescription of opioid medications. The Taskforce is a multidisciplinary and interconnected group of experts, that started in April 2019 and has a mandate of 3 years. It is led by the Institute of Responsible Use of Medicines. The website of the Taskforce's activities (www.opiaten.nl) provides an update and overview all the related news.

The main objectives are to limit the prescription of pain medication where possible and to reduce the number of patient who engage in long-term use of prescription opioids. The overall approach will balance the need of adequate pain management against the potential for opioid dependency. Adjustments in treatment and prescription regulations and have to be nuanced and be patient-oriented in order to not to create unwanted diversion to black market substitutions due to withdrawal symptoms or untreated pain.

The taskforce has started a range of coordinated and targeted activities. Its aims are:

- To increase knowledge and awareness on the issues related to overprescription and overuse of opioid medications.
    - Promote the use of Pharmaceutical Compass, the national guidance on prescription medications
    - Organize special information events for clinicians and pharmacies

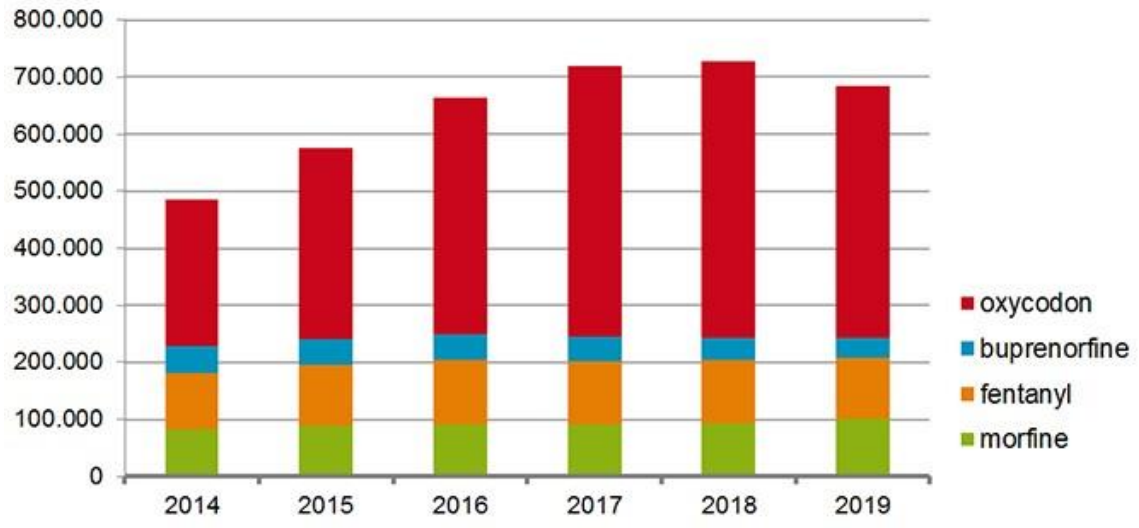
- Promote discussions on opioid medication use at the existing local platform of the of general practitioners and pharmacies (the Pharmacotherapeutic Meetings, FTO) to discuss and address local or regional situation of opioid prescriptions.

- To promote the use of the pain medication prescription procedure from 2018. This procedure describes proper use of pain medication prescription and information. Examples: ○ Pain medication prescription should include a final goal of reducing/stopping of medication ('exitstrategy'). This has to be addressed by 1st prescriber of the medication. ○ Strong pain medications should only be prescribed in hospitals for 5 days.
  - Harmonise existing prescription practices in different health care settings
- To be alert on non-medical or improper use of opioids ○ Support Addiction care institutes to monitor and signal incidents of non-medical use
  - Stimulate the Drugs Information and Monitoring System (DIMS) to be equipped for detection of opioids like fentanyl analogues.

The approach of the Taskforce can be characterized as comprehensive and multi-disciplinary, as it involves professionals from different domains of health care (primary, secondary health care, addiction care, acute and chronic pain management, care providers, prescribers and patients) and targeting different aspects of care.

The first results of the activities of the taskforce are promising.

- The first priority of the Taskforce was to increase awareness of the problematic use and to start actions to prevent long-term use in patients. A range of educational and informational activities for a number of target groups have been development of educational and informational material. For example, e-learning courses and videos addressing the overprescription of opioids were developed for a range of target groups, including clinicians, pharmacist, anesthetists, supportive (non-)medical care staff and patients.
- In 2020 the figures show a decreasing trend in opioid prescriptions for the first time in over a decade. There was a decrease of 6.4% in opioid prescription recipes and in 5.6 % of prescription users (Stichting Farmaceutische Kengetallen, SFK)



3.3.2 Specific SO Research

Targeted research is being funded in the Netherlands to gain more insight into the prescription, medical use, diversion and non-medical use of SO.

The project Tackling and Preventing the Opioid Epidemic (TAPTOE) is a comprehensive package of studies to map diverse aspects the opioid situation and to fill the various gaps in our understanding of the opioid situation in the Netherlands. TAPTOE is a 5 year research programme that started in 2020 and has a set of 13 different interlocked research activities planned on getting detailed insight in the SO prescription practices from prescribers, dispensers and patients' perspective. Other parts of the research will be exploring alternative treatments, regulations and procedures that can contribute to better pain treatment outcomes and that mitigate the addiction risks. The research programme will lead to a better understanding and enhanced responses to the opioid situation in the Netherlands.

3.3.3 Specific SO Health interventions:

Experts, who were interviewed, suggested a number of recommendations to increase the response and intervention capacity in the Netherlands:

- Take-home Naloxone (in nasal or other easy administration modes) could be provided by pharmacies to layman or peer consumers. Additional naloxone provision is recommended by experts in order to be better prepared. This is currently not being practiced in the Netherlands. It is mentioned that this is not required because of good ambulance coverage (accessibility of 95% within 15 mins).
- DIMS may be better equipped for synthetic opioids, such as including SO in the Red Alert. The Red Alert could be more detailed towards information provision on a local level.

3.4 Targeted SO Law enforcement and narcotic control

There is considerable law enforcement effort to tackle large scale drug production, transport and trade, varying from large scale cocaine import in harbor Rotterdam and criminal gang violence to rising methamphetamine production and sophisticated XTC/amphetamine-production infrastructure.

Production: SO are not a specific priority for drug law enforcement, although the recent detection of a lab with 2000 liters of fentanyl precursors dismantled in a region with deep entrenched XTC production infrastructures, raised alarms regarding a potential new trend in which existing drug production infrastructures are repurposed for the production of other drugs in the Netherlands, such as methamphetamine but also SO (October 2020). Police actions are regularly targeting the production infrastructure by tracking production necessities, such as specialized equipment and precursors.

Transit: Incidental seizures of smaller quantities of fentanyl (such as the 1kg Fentanyl found in garden shed in 2020) are probably part of transit and redistribution and indicate the use of the existing criminal infrastructures that are developed for other illegal drug trade (e.g. of cannabis or MDMA)..

Narcotic control: Fentanyl and many of its analogues (e.g. acetylfentanyl, carfentanyl) are regulated by the Dutch opium law. Currently, narcotic control is being conducted by adding a substances to the list of controlled substances. This process is been considered reactive and time consuming. In order to respond more quickly, a new legislation will be implemented in the Netherlands within the next 1-2 years. The new ban on NPS will include groups of substances, of which one will be fentanyl-like SO. Similar type of NPS laws have been in force in for example Belgium, UK, Austria, Hungary, Croatia, Ireland, Sweden and Germany. The draft law is now under review.

There are some concerns mentioned regarding the impact of the law. Firstly the planned generic ban in the Netherlands will cover fentanyl-type opioids, and **not** other synthetic opioids. The problem is that fentanyllike NPS have recently been decreasing, while non-fentanyl SO (like U-47700) have been increasing in Europe, probably caused by the new tight legal restriction in China. Vigilance and good monitoring will be key to not miss a new trend. Secondly, studies abroad indicate a temporary barrier in trade, as it often leads to an increase and shift in towards illegal and/or non-classified substances and probably negative health results.

4. Conclusions and recommendations

4.1 Current situation

While illegal novel SO are not a major concern in the Netherlands, the overprescription of (legal) opioids has received a lot of attention in recent years. After over a decade of increases in prescribed opioids, there is now a slow downward trend. The coordinated government action to reduce overprescription and overuse of SO seems to have positive results, although concerns remain on whether some patients will turn to diverted prescription opioids from the Internet.

Professionals acknowledge that the biggest problem is that they have no insight into the group of people who use SO recreationally or who purchase diverted prescription opioids to feed their dependence. This is the biggest monitoring challenge that currently seems very difficult to address. Moreover, there are worrying signs of increased domestic production and availability of illegal SO in the Netherlands, potentially driven by the currently changing dynamics in drug gangs and markets in the Netherlands.

4.2 Monitoring

The Netherlands has a well-developed monitoring system to surveille the use of and incidents with illegal drugs. The overall system is arguably one of the most advanced in Europe.

Strong elements of the monitoring system include:

- A variety of sources that allow for refined triangulation ○ Use of qualitative and quantitative methods ○ Input from both health and law enforcement agencies
- Combination of international established good practices and more innovative methods (like drug checking).
- The monitoring system is a dynamic process, which has been continuously improved with new sources of information
- A mandated multi-disciplinary risk assessment committee that provides evidence-informed advice to the government.

Weaker points and needs in the monitoring system:

- There is no monitoring on the use of the illicit-SO using population (both illegal as well as diverted prescription medications). Therefore, there is limited insight into the size, background and motives of users of SO.
- The decision making process at the Ministry is not fully transparent. Less evidence-based motives (for instance to satisfy certain concerns in the general public order) are also part of public policy making.

4.3 Targeted government health responses

The overprescription and overuse of strong pain medications, which is considered the biggest SO-problem in the Netherlands, is currently being addressed. The underlying approach of all actions is to develop a *balanced* approach and avoid potential adverse side effects, such as the abrupt stopping of treatment which might lead to people seeking their opioids elsewhere. The activities promote effective measures to prevent the abuse of opioids, while keeping effective pain management available for those patients who need them. The increased overall awareness and the coordinated SO action through a specific Opioid Taskforce are currently showing initial results.

The dedicated Taskforce is a well-designed, coordinated and multidisciplinary approach to start a range of coordinated actions to effectively address the situation. Essential element is the sense of *shared ownership* among all stakeholders, based on common interests and collaborative actions and which leads to active involvement and commitment of all involved actors. There are indications that the activities initiated by the Taskforce are paying off and prescription rates are curbing down.

In addition to the direct action, money has been allocated to a number of research projects on the prescription of opioids, such as TAPTOE. These research activities aim to provide knowledge in the gaps in understanding of the SO problem in the Netherlands. The research is likely to contribute to better understanding of the overall SO situation and particular information gaps. It will hopefully also contribute to the further improvement of quality health care.

4.4 Narcotics Control and Law Enforcement

Although law enforcement does not currently see SO as a priority, they are always alert and regularly receive updates on whether there are signs of increased SO. If SO should ever increase, professionals in the law enforcement sector claim that SO will immediately become a priority, given the frightening images from North America.

A generic ban on NPS will be introduced in 2021 or 2022. This will include the group of fentanyl-like SO. However, caution is in order as Europe has seen a shift towards non-fentanyl SO in 2019 and the market supply is likely to adjust to the changes in the law.

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