The MEDICRIME Convention La Convention MÉDICRIME



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AN ASSESSMENT OF PUBLICLY REPORTED INCIDENTS OF ILLICIT DIVERSION AND FALSIFICATION OF MEDICINES

Countering falsified medical products - Global programme (CRIMFAMED Project)

MEDICRIME Unit

Directorate General I- Human Rights and Rule of Law



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Executive Summary

This paper has been produced in support of the Project entitled "Countering Falsified Medical Products Global programme" (hereinafter, CRIMFAMED) which aims at promoting the MEDICRIME Convention. The challenge faced by authorities in preventing, detecting, and responding to reports of the illicit diversion of authorised medicines and the identification of falsified versions of legitimate medicines are significant. These challenges include protecting the patient and wider public health whilst ensuring the security of the regulated supply chain both in terms of preventing falsified medicines entering the supply chain but also in preventing medicines being intentionally removed from the intended supply chain and diverted into an unintended supply chain in another country or to the illicit market.

Through open-source online research, i.e. publicly available information, the intention of this paper is to identify those medicines which have been more commonly subject of illicit diversion or falsification reports.

From the information gathered during the preparation of this paper it is suggested that:

- reported incidents indicate that controlled medicines appear more generally at risk to both illicit diversion and falsification;
- falsified controlled medicines often contain undisclosed high-risk ingredients;
- falsified controlled medicines have been reported to have contributed to fatal outcomes in many differing contexts;
- illicit diversion maybe a threat indicator of future risk of the production of falsified versions of the diverted product;
- whilst limited to publicly available information, reported incidents are suggestive of high-income countries being most at risk of the illicit diversion and falsification of controlled medicines;
- regulated supply chain losses and thefts may play a significant role in illicit diversion.

To allow States to develop evidence-based policies three key areas may require further consideration and development to resolve:

- limited availability of data/ comprehensive data set;
- limited research of the topic and sub-topics;
- a paucity of detailed analysis to inform focus and direction.

1. INTRODUCTION

1.1. Objective

The purpose of this paper is to research differing types of medicines and identify those products that have been or are more commonly the subject of reported incidents of illicit diversion from the regulated supply chain and/or are the victim of the production of falsified versions of legitimate medicines.

1.2. Methodology

The approach that has been adopted to compile this paper:

- 1. to conduct online open-source research, i.e. intelligence produced from publicly available information;
- 2. to categorise in tabular form identified products into 3 sections, medicines (generally available and not controlled under the international conventions as psychotropic or narcotic), controlled medicines, and psychoactive products and other substances presented as "medicines", "drugs", etc for gaining a "high" without any therapeutic benefit, indicating whether it has been subject of illicit diversion and/or falsification;
- 3. provide a narrative on each of the identified products based upon the findings of the open-source research;
- 4. provide source links to all identified issues to develop an evidence-base and facilitate the reader to conduct further detailed research;
- 5. to create a repository of links to identified incidents by product (appendix 1);
- 6. to conclude by identifying themes or strategic issues that emerge across the entirety of the paper.

The following definitions have been used for the delivery of the described methodology:

• Medicinal product (medicine):

- any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals;
- any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring, correcting, or modifying physiological functions by exerting a pharmacological, immunological, or metabolic action, or to making a medical diagnosis¹.

¹ Article 4.b. Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health. (2011). Council of Europe Treaty Series- No. 211. https://rm.coe.int/168008482f

- **Controlled medicines:** pharmaceuticals with an identified or emergent clinical application whose active principles are listed under one of the three international drug control conventions².
- **Psychoactive drugs**: substances that, when taken in or administered into one's system, affect mental processes, e.g. perception, consciousness, cognition or mood and emotions. Psychoactive drugs belong to a broader category of psychoactive substances that also include alcohol and nicotine. "Psychoactive" does not necessarily imply dependence-producing, and in common parlance, the term is often left unstated, as in "drug use," "substance use" or "substance abuse."³
- **Illicit diversion**: The unsanctioned intentional supply of medicines from legal sources to the illicit drug market, or to a market or user for whom the drugs were not intended.
- **Falsified medical products**: Shall mean a false representation as regards identity and/or source⁴.

1.3. Limitations

This paper is limited to incidents and content which has been released by authorities and other publicly available online information and does not propose to be an exhaustive assessment of all relevant global incidents.

2. **REPORT FINDINGS**

This report is presented in three sub-sections. The first offers a visual presentation (table 1) which lists products identified as subject of reported incidents of illicit diversion and/or falsification divided into the three categories which this paper will focus upon:

- Medicines
- Medicines that are subject to further controls
- Psychoactive and other substances

The second section provides an additional narrative on the nature of the reports of illicit diversion and falsification of the products concerned and the source from which the information has been identified. Each of the identified sources provides more detailed information on the individual incident, criminal methodology and volumes of the named product involved. To conclude the report the information gathered during this research is drawn to together to provide some higher-level findings.

² The Convention on Narcotic Drugs of 1961, as amended by the 1972 protocol, The Convention on Psychotropic Substances (1971) & UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988)

³ See: <u>https://www.who.int/health-topics/drugs-psychoactive#tab=tab_1</u>

⁴ Article 4.j. Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health. (2011). Council of Europe Treaty Series- No. 211. https://rm.coe.int/168008482f

2.1. Product Identification

Each of the columns within the table list products which have been the subject of illicit diversion or falsification reports identified from open-source media. The products listed should not be interpreted as a definitive list, but as a general indicator of incidents reported within the media. Alongside each of the product names an additional indicator (D = Diversion, F = Falsification) is added to aid the reader identify the nature of the incidents connected to each specific product.

Table 1: List of products subject to identified reported incidents of illicit diversion and/or falsification.

Medicines (Diversion and/or Falsification)	Controlled Medicines (Diversion and/or Falsification)		Psychoactive and other substances
Erectile dysfunction Viagra®/ Cialis® F	Oxycontin®/ oxycodone D&F		Captagon
Antibiotics/ anti- inflammatory F	Dilaudid®/ hydromorphone D&F		Nitazenes
Semaglutide Ozempic® D&F Saxenda®	Xanax®/ alprazolam D&F		Etizolam
Botox® F	Diazepam	D&F	Xylazine
Anti-malarial D&F	Tramadol	D&F	
	Zopiclone/ Zolpidem	D&F	
	Buprenorphine/ Sub	utex D	
	Pregabalin/ Gabape	entin D	
	Adderall®	D&F	
	Fentanyl	D&F	
	Ketamine	D&F	
	Tilidine	D	

2.1.1. Analysis of the nature of incidents reported

The following section highlights examples of:

- The unsanctioned intentional supply of regulated supply chain medicines from legal sources to the illicit market.
- The illicit diversion of medicines that are then placed on the market of countries which were not the intended recipients and/or not authorised there.
- The seizure of falsified versions of licensed medicines.

These examples are based upon publicly available open-source media reports which are by their very nature restricted to those cases where relevant authorities determined it to be appropriate to release such details.

The source of the medicines illicitly diverted are in the main obtained from the regulated supply chains of high-income countries (HIC) and are then sold within the illicit market for non-medical use within other HICs to maximise criminal profit. An example of a highly sophisticated illicit diversion criminal enterprise was reported in Poland where an organised criminal group (OCG) was diverting controlled medicines not only from the Polish supply chain but products from other nearby country supply chains. The controlled medicines were then illicitly sold to numerous countries including the USA⁵. This example is a truly transnational organised illicit diversion operation.

The falsification of licensed medicines provides a continual threat to public health and the regulated supply chain. A report released by the Royal Canadian Mounted Police (RCMP) highlighted their assessment of the increased consumption of what was described as 'counterfeit drugs'⁶. The report illustrates medicines assessed as the most likely to be subject of falsification and widely available within the illicit market. It is noted that the majority of these medicines are controlled medicines, as previously highlighted, subject of additional controls:

- **Benzodiazepines:** mainly prescribed to treat anxiety and insomnia; examples include lorazepam (Ativan[®]), alprazolam (Xanax[®]), diazepam (Valium[®])
- **Psychostimulants:** mainly prescribed to treat attention deficit disorder and attention deficit hyperactive disorder (ADD/ADHD); examples include methylphenidate (Ritalin[®], Adderall[®]) and lisdexamfetamine (Vyvanse[®])
- **Opioids:** mainly prescribed to treat chronic pain, serious injuries, or pain after surgery; examples include oxycodone (Oxyneo[®]), hydromorphone (Dilaudid[®]), fentanyl and codeine
- Erectile dysfunction drugs: mainly prescribed to treat erectile dysfunction; examples include sildenafil (Viagra[®]) and tadalafil (Cialis[®])

The US Drug Enforcement Administration (DEA) also recognises the threats posed by falsified medicines and has produced a 'Fake Pills Fact Sheet'⁷ which highlights the following:

• Many fake pills are made to look like prescription opioids – such as oxycodone (Oxycontin®, Percocet®), hydrocodone (Vicodin®), and alprazolam (Xanax®); or stimulants like amphetamines (Adderall®) – but contain fentanyl or methamphetamine.

Following research, a number of specific medicines, controlled medicines and psychoactive and other substances have been identified as being subject of global reporting of illicit diversion and/ or falsification. The next section provides narrative detail on the nature of incidents involving these products and links to the source information.

⁵<u>https://cbsp.policja.pl/cbs/aktualnosci/215101,Leki-zawierajace-substancje-psychotropowe-wysylano-min-do-USA-rozbity-gang.html</u>

⁶ https://www.rcmp-grc.gc.ca/en/qc/increase-the-consumption-counterfeit-drugs

⁷ <u>https://www.dea.gov/factsheets/fake-prescription-pills</u>

2.2. Controlled Medicines – Overview

A recent study found that there has been a noted increase in the use of synthetic opioids in Europe relating in particular to oxycodone, fentanyl and tramadol⁸. This publication was underpinned by the European Drugs Agency publication 'EU Drug Market: Heroin and other opioids — Trafficking and supply'⁹. Amongst the reporting of a range of drug seizures were specific details of seizures of opioid medicines. The seizures of oxycodone, tramadol, methodone and buprenorphine amounted to many 1000's per annum within Europe. To provide some context, in 2021 there were 7927 reported seizures of these products amounting to 2,412,776 doses.

In seeking to understand illicit availability and supply of controlled medicines, the Global Initiative Against Transnational Organised Crime (European Drugs Trends – issue 1)¹⁰ brought together significant analysis of illicit trading of controlled and falsified medicines and developed an assessment of the scale of the issues from a European perspective. Investigation of the online European environment supported the above quoted findings and identified widespread availability of prescription of opioids, including tramadol, oxycodone, tilidine, fentanyl patches and prescription grade fentanyl tablets.

This was based upon examination of Dutch retail channels on Telegram in September 2024 identifying 46 different offerings of oxycodone at an average price of $\in 8.67$ per tablet with discount for bulk purchases, an indicator of the volume of illicit product availability. The average price for a Tramadol pill was $\in 1.41$. Analysis of 21 Telegram drug retail channels in Germany discovered offerings of oxycodone at an average price of $\in 9.02$ per pill and Tramadol for $\in 0.71$.

The geographical spread of illicit availability of prescription opioids in this research included multiple European countries such as Spain, Romania, UK, Germany, Ukraine, and the Netherlands.

A limitation of this research was the lack of forensic analysis of the products being offered for sale. Whilst the products presented as pharmaceutical grade legitimately manufactured goods, without detailed analysis the presence of falsified products or simply scam advertising could not be eliminated. However, for the purposes of this paper, the online offering of the illicit sale of diverted or falsified products is highly significant.

In terms of potential sources of the controlled medicines being offered for sale, the authors concluded they are acquired via medical prescriptions, pharmacies, hospitals, production sites, theft, and diversion.

⁸ https://www.consilium.europa.eu/en/policies/opioids-drugs-heroin/

⁹ https://www.euda.europa.eu/sites/default/files/pdf/31629_en.pdf?571720

¹⁰ <u>https://globalinitiative.net/wp-content/uploads/2024/12/Observatory-of-Organized-Crime-in-Europe-European-Drug-Trends-Monitor-Issue-1-GI-TOC-December-2024.v3.pdf</u>

Overall findings of this research included:

- There is a widespread market for prescription opioids
- Little data exists about the non-medical usage of prescription opioids
- Issues relating to prescription opioids 'attracted far less awareness and research compared to other so-called 'new psychoactive substances' (p3)

Finally, and potentially a high-risk illegal market demand driver, this research assessed that prescription opioids are much cheaper than illicit non-pharmaceutical opioids.

The following narrative provides examples of a range of reported issues involving differing controlled medicines.

2.2.1. Oxycontin®/ oxycodone

Incidents of organised and high-volume illicit diversion of Oxycontin® and generic oxycodone versions have been widely reported in the media. As previously described illicitly diverted product is subsequently sold into the illicit markets of HICs. Within Europe an example was reported by Finnish Police who released a public statement as part of a criminal investigation. The Oxycontin® seized originated from the Polish regulated supply chain, diverted, and then entered Finland leading to a criminal investigation¹¹. Across Europe, there have been a number of reports by authorities of the illicit diversion of Oxycontin®/ oxycodone. In the main, the diverted product was destined for the USA but also to other European illicit markets. The following sources are examples highlighting such reporting:

- https://www.ilgiorno.it/cronaca/traffico-ossicodone-stati-uniti-arresti-03e118d4
- https://www.fanpage.it/milano/spacciava-ossicodone-e-morfine-online-arrestato-un-ragazzo-di-22-anni/
- https://www.france24.com/en/live-news/20210519-italy-police-dismantle-drug-ring-sending-opioids-to-us

Whilst the USA has been identified in the above reports as the destination for illicitly diverted products it has also been the source of diversion within the country. There are numerous reports involving the illicit diversion of oxycodone involving, on occasions, healthcare professionals and prescription scams:

- https://www.dea.gov/press-releases/2024/03/01/nurse-practitioner-sentenced-70-months-unlawful-drug-distribution
- https://www.dea.gov/press-releases/2024/03/05/psychiatrist-sentenced-48-monthsunlawful-distribution-controlled

All of these incidents highlight the use of the criminal market to sell the diverted controlled medicines.

¹¹<u>https://poliisi.fi/en/-/a-crime-investigation-related-to-a-highly-dangerous-new-drug-moved-to-the-consideration-of-charges</u>

Oxycontin®/ oxycodone products have also been subject of reports of falsified versions being seized by authorities. A common trend highlighted in many reports, following forensic analysis of seizures, has been the identification of undisclosed dangerous ingredients. A reported case from Canada disclosed the seizure of, amongst a number of falsified controlled medicines, 112,000 falsified Oxycontin® tablets which following analysis were identified as containing Fentanyl, Carfentanil, Para-Fluorofentanyl, and Heroin¹².

A media release by Canadian authorities stated "*The drug is so cheap, virtually every pill sold* on the street today stamped as a CDN 80 oxycodone tablet actually contains fentanyl^{"13}.

Similar reports have been identified within public health information in Australia (containing isotonitazepyne)¹⁴ and New Zealand¹⁵ (containing metonitazene) where falsified versions of oxycodone have been seized.

Reports in Europe have also mirrored the issues identified within North America. The UK has reported seized falsified versions of oxycodone which, following analysis, were identified as containing additional dangerous ingredients, e.g. nitazenes¹⁶. Seizures of falsified versions of this product have been made in other European countries which have resulted in public health warnings being issued by authorities¹⁷. Forensic analysis in European countries also identified additional dangerous ingredients including metonitazen and protonitazeen¹⁸.

A more recent development, identified following the seizure of falsified versions of Oxycontin®, is a growing suggestion that the illicit diversion of a product increases the risk of the same product being subsequently falsified. Following analysis of recent seizures of falsified 80mg Oxycontin® it was discovered that the tablets were contained in primary and secondary packaging displaying batch numbers and expiry dates that related to a previously widely diverted batch of 40mg Oxycontin® (source: Mundipharma)¹⁹. The issue is subject to broader debate and awareness raising by others focused upon falsified medicines and maybe, an indicator of an increasing risk to the effective prevention of the illicit diversion of medicines from the regulated supply chain²⁰.

¹² <u>https://bc-cb.rcmp-grc.gc.ca/ViewPage.action?contentId=83119&languageId=1&siteNodeId=2307</u>

¹³ https://www.rcmp-grc.gc.ca/en/gazette/were-dead?fent

¹⁴ <u>https://www.health.nsw.gov.au/aod/public-drug-alerts/Pages/nitazenes-fake-oxycodone-nov24.aspx</u>

¹⁵ <u>https://thelevel.org.nz/news-and-stories/fake-yellow-oxys-what-you-need-to-know</u>

¹⁶ https://www.bbc.co.uk/news/articles/c4nn25qzel3o

¹⁷<u>https://polisen.se/aktuellt/pressmeddelanden/2024/augusti/farlig-drog-saljs-i-falsk-forpackning-i-karlstad/</u>

¹⁸ https://crime-nieuws.nl/zeer-gevaarlijke-synthetische-drugs-100x-sterker-dan-heroine-voor-heteerst-aangetroffen-in-nederland/

¹⁹ https://cbsp.policja.pl/cbs/aktualnosci/215101,Leki-zawierajace-substancje-psychotropowe-wysylano-min-do-USA-rozbity-gang.html

²⁰ <u>https://truemedinc.com/blog/the-early-warning-signs-of-counterfeiting-how-diversions-signal-the-beginning-of-a-bigger-problem/</u>

The images below (figure 1) relate to the falsified packaging referenced above.



Source: Mundipharma

2.2.2. Dilaudid®/ hydromorphone

Reports relating to the illict diversion of Dilaudid® or the generic version hydromorphone, a morphine-based opioid, highlight other broader themes in addition to illicit diversion. Of note is the volume of what is reported as 'unexplained losses of prescription drugs'²¹ within the regulated supply chain and are on occassions of large volume. The product has been subject of wide spread reports of diversion from the regulated supply chain into the illicit market. Media reports and information released by Canadian Authorities has described seizures of supply chain product as part of law enforcement activity²².

The availability of the regulated supply chain product has been reported in the Canadian media:

- <u>https://www.cbc.ca/news/canada/london/serious-challenges-caused-by-opioid-prescription-diversion-london-police-chief-tells-mps-1.7394075?</u> cldee=G-6hJ-<u>tTHeg1 huoOncTeYRtqtUPKEzkh0tHhkTn7w03980X97qbxk OtoJFNEe1&recipienti</u> <u>d=contact-3106f09eba0bef119f89000d3ae9a76d-</u> ece197acc598490f85cd8f5c5f958122&esid=17aaaf19-cdac-ef11-8a6a-6045bd5dff62
- <u>https://www.cbc.ca/news/canada/london/about-half-of-opioids-seized-by-london-ont-police-last-year-were-prescribed-dilaudids-1.7255324</u>

Like oxycodone, there are reports of falsified versions of hydromorphone seized by law enforcement and again, following forensic analysis, additional dangerous ingredients being discovered, e.g. fentanyl²³. Such seizures are often made with other large quantities of falsified controlled medicines.

2.2.3. Xanax®/ alprazolam

Many of the reports relating to Xanax® or the generic version, alprazolam, highlight the scale of falsified products sold within the illicit markets. In a recent case reported in the USA,

²¹ https://www.cbc.ca/news/canada/unexplained-losses-prescription-drugs-1.7247602

 ²²<u>https://bc-cb.rcmp-grc.gc.ca/ViewPage.action?siteNodeId=2136&languageId=1&contentId=83067</u>
 ²³ <u>https://bc-cb.rcmp-grc.gc.ca/ViewPage.action?contentId=86054&languageId=1&siteNodeId=2114</u>

convicted persons engaged in a conspiracy to sell directly to customers on darknet marketplaces. The Court held one of those convicted was responsible for the distribution of more than 16.1 million counterfeit alprazolam tablets from 2017 to 2022 and was ordered to forfeit more than \$6.9 million²⁴. The falsified versions of alprazolam were found to contain clonazolam and etizolam.

The threat posed by falsified versions of such products has resulted in tragic outcomes where purchasers of these products within the illicit market have died, such as the case involving a young man called Jake Beddoe who purchased what was thought to be a Xanax® tablet, only to die from a fentanyl overdose²⁵.

Similar issues of the supply of falsified products to those reported in the USA have also emerged within Europe. A recent prosecution highlighted the industrial scale of falsification production and international supply of the product, described by police that *"Forensic evidence found at the scenes suggested a major production of Alprazolam, a medicine within Xanax, possibly at a rate of 10,000 pills an hour"*²⁶.

The Therapeutic Goods Administration (TGA) of Australia issued an alert highlighting falsified versions of alprazolam 2mg tablets and another alprazolam containing product named Kalma 2 (see figure 2)²⁷



Source: <u>https://www.tga.gov.au/news/safety-alerts/counterfeit-alprazolam-2mg-and-kalma-2-tablets</u>

A more recent report in Australia highlighted the death of two people following the ingestion of falsified Xanax® in the state of Queensland. The tablets were reported to contain protonitazene and bromazolam (a novel benzodiazepine)²⁸. Figure 3 provides images of legitimate Xanax® and the falsified version.

²⁴<u>https://www.irs.gov/compliance/criminal-investigation/florida-man-and-woman-sentenced-for-conspiracy-to-sell-counterfeit-drugs-on-dark-web</u>

²⁵ <u>https://www.safemedicines.org/2020/11/jake-beddoe.html</u>

²⁶ <u>https://www-bbc-com.cdn.ampproject.org/c/s/www.bbc.com/news/articles/c3ggdew76gzo.amp</u>

²⁷ <u>https://www.tga.gov.au/news/safety-alerts/counterfeit-alprazolam-2mg-and-kalma-2-tablets</u>

²⁸ https://insight.qld.edu.au/news/drug-warning-fake-xanax-containing-a-strong-opioid

Figure 3



Source: https://insight.qld.edu.au/news/drug-warning-fake-xanax-containing-a-strong-opioid Further reports from New South Wales, Australia provided images of falsified versions of Xanax® and alprazolam (figure 4). It is noted that these falsified versions have been identified within falsified packaging increasing risks to the regulated supply chain²⁹.



Source: https://www.health.nsw.gov.au/aod/public-drug-alerts/Pages/counterfeitalprazolam.aspx

The New South Wales Health Administration hosts an online health alert repository which highlights increasing numbers of falsified medicinal products have been identified as containing nitazenes³⁰.

In addition to the wide-ranging reports of falsified versions of Xanax® and alprazolam, there have also been reports of the illict diversion of legitimate regulated supply chain versions³¹. Such cases often involve a number of additional illicitly diverted controlled medicines and, on occasions, involve licensed healthcare professionals acting illegally within the regulated supply chain system. A case from the USA highlighted this methodology where a physician wrote prescriptions for oxycodone, methadone, and alprazolam in exchange for cash. The physician was sentenced to 10 years imprisonment³².

²⁹ <u>https://www.health.nsw.gov.au/aod/public-drug-alerts/Pages/counterfeit-alprazolam.aspx</u>

³⁰ https://www.health.nsw.gov.au/aod/public-drug-alerts/Pages/default.aspx

³¹<u>https://cbsp.policja.pl/cbs/aktualnosci/215101,Leki-zawierajace-substancje-psychotropowe-wysylano-min-do-USA-rozbity-gang.html</u>

³²<u>https://www.dea.gov/press-releases/2024/05/24/doctor-sentenced-10-years-prison-selling-opioid-prescriptions</u>

2.2.4. Diazepam

Diazepam has been subject of numerous reports of both falsification and illict diversion. The UK identified significant diversion of diazepam out of the UK regulated supply chain and into the illicit market. The UK's medicine regulator, Medicines and Healthcare Regulatory Agency (MHRA), instigated 19 investigations following the identification of an extensive network of criminality involving businesses such as wholesale dealers and a small number of registered pharmacies throughout the UK illegally diverting medicines³³. It was estimated that between 2013 and 2016 around £115-200m of medicines were diverted from the legitimate supply chain onto the criminal market.

For example, a prosecution reported in a 2024 involved the illegal diversion of benzodiazepines and illustrates this trend: a community pharmacy in the UK procured 55 million doses of various medicines, including 47 million doses of diazepam, over a four year period. The Court found that the diversion and subsequent selling of the controlled medicines outside of the regulated supply chain as on an 'industrial scale.' To contextualise the scale of this diversion, in 2014, only 5 million doses of diazepam were legally dispensed across the entirety of England³⁴. The two pharmacists involved in this case pleaded guilty to supplying controlled drugs were sentenced to two years' imprisonment each, suspended for 24 months, at Southwark Crown Court, London.

The UK BBC television documentary series entitled 'Drugs Map of Britain' included an episode entitled 'Scotland's Valium Crisis'³⁵ and highlighted how the illicit market supplies various forms of diazepam, including legitimately manufactured and diverted versions of diazepam supplied by criminal actors, along with unlicensed, sub-standard and falsified versions, catering to those individuals seeking such substances. Recent reports have highlighted cases with serious outcomes where individuals have purchased what they believe to be controlled medicines from illicit sources which are later discovered to contain ingredients such as nitazines³⁶.

Reports on the impact of falsified versions of diazepam also include fatal outcomes due to the dangerous ingredients³⁷. The report into this case highlighted an assessment by the Police Service of Northern Ireland that '10,000 fake diazepam tablets' are shipped into Northern Ireland each week. Further reported in Ireland was a cluster of overdoses in Dublin, Galway, and the Mid- West. It was concluded that falsified benzodiazepine tablets containing nitazene were associated with the overdoses³⁸.

The New South Wales Health Administration has issued warnings following the identification of falsified versions of diazepam from illicit sources found to contain other ingredients, e.g.

³³ <u>https://www.gov.uk/government/news/mhra-cracking-down-on-organised-crime-worth-200m</u> ³⁴ <u>https://www.gov.uk/government/news/pharmacists-who-illegally-supplied-more-than-55-million-doses-of-controlled-drugs-sentenced</u>

³⁵ https://www.youtube.com/watch?v=45JevY9hEOc

³⁶ <u>https://www.bbc.com/news/articles/c24pqrrg8q0o</u>

³⁷ <u>https://www.bbc.co.uk/news/uk-northern-ireland-36297527</u>

³⁸ <u>https://www.irishexaminer.com/news/arid-41416816.html</u>

bromazolam, paracetamol and caffeine³⁹. Similar reports have been identified in New Zealand this time containing N-Desethyletonitazene, again a nitazene⁴⁰.

In an article entitled 'Counterfeit benzodiazepines—A phantom menace,' published in the International Journal of Clinical Practice, the issue of falsified benzodiazepines was explored. The authors highlighted:

- benzodiazepines are becoming increasingly more available on the black market.
- the prevalent active pharmaceutical ingredient (API) substitutes in counterfeit benzodiazepine tablets is etizolam linked to numerous acute intoxications, including deaths.

The article went on to highlight the identification of what the authors described as "*rather convincing counterfeits of TEVA-brand Diazepam pills (10 mg, 500 pill bottle) that could potentially deceive not only the intended consumers, but even medical professionals*". This highlights the risk to not only public health through non-medical usage but also the regulated supply chain and legitimate sources of medicines. The authors, working with the Czechia police and the manufacturer, identified a high-level dark web distributor accounts. Following a test purchase of an identical product, further enquiries concluded that:

- the tablets test purchased contained etizolam rather than diazepam.
- the falsified version was being produced and distributed at near-industrial scale.
- this account alone had sold over two million falsified benzodiazepine tablets throughout Europe (Xanax® and diazepam) over a year period (09/2018-10/2019).
- an assessment of the account's market logs identified that many sales were large batches (45 orders totalling at/over 10,000 tablets) indicating a suspected intention for further resale⁴¹.

The scale of the threat involving falsified benzodiazepines was further displayed following enforcement activity in the UK. Reported by the local police force:

"Specialist equipment seized and arrests made following counterfeit drugs manufacturing crackdown"⁴²

As part of enforcement action four persons were arrested and specialist manufacturing equipment to produce large volumes of falsified prescription medicines were seized. Additionally, 2.6 million benzodiazepine tablets were also seized. The sophistication of this operation can be seen in the images released by the police (figure 5). In addition, it is noted that the falsified products were in blister pack packaging raising increased risk to purchasers and potential regulated supply chain breaches.

 ³⁹ <u>https://www.health.nsw.gov.au/aod/public-drug-alerts/Pages/counterfeit-diazepam-may24.aspx</u>
 ⁴⁰ <u>https://thelevel.org.nz/news-and-stories/potent-opioid-found-in-fake-diazepam</u>

⁴¹ Jurásek. B., Čmelo. I., Hájková. K., Kofroňová. E. & , Kuchař. M. (2020). Counterfeit benzodiazepines—A phantom menace. International Journal of Clinical Practice. Wiley.

⁴² <u>https://www.gmp.police.uk/news/greater-manchester/news/news/2022/may/specialist-equipment-seized-and-arrests-made-following-counterfeit-drugs-manufacturing-crackdown/</u>

Figure 5



Source:

https://www.gmp.police.uk/news/greater-

manchester/news/news/2022/may/specialist-equipment-seized-and-arrests-made-followingcounterfeit-drugs-manufacturing-crackdown/

2.3. Other controlled medicines

In addition to the controlled medicines highlighted above many other controlled medicines were identified as being subject to illicit diversion and/or falsification. The following section provides further examples.

2.3.1. Examples

The illicit availability of **Buprenorphine/ Subutex** is well known to European authorities forming part of the initial area of focus of Europol's Operation Mismed and in particular an illicit trade between France and Finland⁴³. The European Drugs Agency publication 'EU Drug Market: Heroin and other opioids — Trafficking and supply'⁴⁴ reported seizures of oxycodone, tramadol, methodone and buprenorphine amounting to many 1000's per annum within Europe.

As part of a wider investigation into the illicit diversion of controlled medicines from the regulated supply chain⁴⁵, UK authorities investigated the diversion of large volumes of controlled medicines authorised to aid sleeping. One investigation focused upon the illicit diversion of **zopiclone**. The outcome of the investigation and prosecution by UK authorities resulted in two pharmacists being sentenced to terms of imprisonment of 27 months and 30 months, respectively. It was assessed that around 600,000 doses were unaccounted for between 2015 and 2016 with an estimated black-market value of around £600,000⁴⁶. In

⁴³<u>https://www.europol.europa.eu/media-press/newsroom/news/millions-of-medicines-seized-in-largest-operation-against-trafficking-of-misused-medicines</u>

⁴⁴ https://www.euda.europa.eu/sites/default/files/pdf/31629 en.pdf?571720

⁴⁵ <u>https://www.pharmalogisticsiq.com/supply-chain-security-track-trace/news/mhra-makes-40-arrests-in-medicine-diversion</u>

⁴⁶<u>https://www.gov.uk/government/news/pharmacists-jailed-for-a-combined-total-of-57-months-for-illegal-supply-of-prescription-medicines</u>

another UK related investigation, an individual was imprisoned for a total of three and a half years for illegally importing unlicensed medicines to the UK including zopiclone⁴⁷. In Ireland, approximately €1.976m of illegal tablets (zopiclone and alprazolam) were seized by law enforcement following searches Dublin⁴⁸.

In addition to reports of the illicit diversion of zopiclone, there have also been reports of incidents involving falsified versions. An example was reported in the UK where two people died and two further people were hospitalised following consumption of suspected falsified medicines including zopiclone⁴⁹.

Adderall is a prescription medicine that doctors commonly prescribe to treat attention deficit hyperactivity disorder, or ADHD. Adderall can also help treat narcolepsy, which is a sleep disorder⁵⁰. However, there have also been non-medical usage reports of other purposes for the product, such as weight loss⁵¹.

There have been widespread reports of illicit trading and falsification of Adderall. In the USA, a telehealth company faced charges accused of distributing over 40 million Adderall tablets 'for no legitimate medical purpose'⁵².

As part of a wider organised crime investigation Canadian authorities seized 23,000 falsified Adderall tablets containing methamphetamine⁵³. In addition, a media report released by the Royal Canadian Mounted Police highlighted an increasing trend of consumption of falsified medicines in Canada including Adderall⁵⁴.

Reports from the USA highlight increasing potential risks involving Adderall. Reported shortages of the product within the supply chain and increased availability online of falsified versions, often adulterated with methamphetamine, have increased public health risks⁵⁵.

The following are links to some examples that provide insight into the scale and threat of the falsification of Adderall within the USA:

- https://www.safemedicines.org/2012/05/fda-warns-about-counterfeit-version-of-tevasadderall.html
- https://www.safemedicines.org/2021/10/fake-adderall.html
- https://www.safemedicines.org/2018/12/bay-area-adderall-counterfeiter-sentencedto-10-years-in-prison.html

⁴⁷ <u>https://www.gov.uk/government/news/man-who-illegally-imported-unlicensed-medicines-from-india-the-middle-east-and-the-far-east-sentenced</u>

⁴⁸ <u>https://www.bbc.co.uk/news/articles/cy4d2974k12o</u>

⁴⁹ https://www.bbc.co.uk/news/uk-england-leeds-59620681

⁵⁰ <u>https://www.medicalnewstoday.com/articles/325646</u>

⁵¹ <u>https://www.bbc.co.uk/news/entertainment-arts-55679233</u>

⁵² https://www.bbc.co.uk/news/articles/cd11qr67qj6o

⁵³ <u>https://bc-cb.rcmp-grc.gc.ca/ViewPage.action?contentId=83119&languageId=1&siteNodeId=2307</u>

⁵⁴ https://www.rcmp-grc.gc.ca/en/qc/increase-the-consumption-counterfeit-drugs

⁵⁵ https://www.safemedicines.org/2024/01/jan-21-2024.html

The number of people being diagnosed with ADHD continues to increase alongside demand for the product⁵⁶. As a result, Adderall and other similar products are increasingly likely to be at risk of illicit diversion or falsification.

Pregabalin is used to treat anxiety, epilepsy, and nerve pain⁵⁷. However, there is significant demand for pregabalin within the illicit market which was highlighted within a UK documentary 'Belfast's Pregabalin Addiction'⁵⁸. Australia's annual overdose report for 2023 reported 887 deaths linked to pregabalin between 2000 and 2021⁵⁹ whilst Scotland reported 502 deaths linked to pregabalin and the similar drug gabapentin in 2020⁶⁰.

Responding to reported incidents of theft French authorities conducted an investigation into the theft of 600,000 doses of pregabalin. In December 2024, four individuals were arrested after a further theft of two pallets of pregabalin and 245,000 doses of pregabalin (estimated value of 750,000 euros) were recovered⁶¹. Further to this incident, a separate investigation, also in December 2024, involving Greek and French authorities working with Europol, seized 3,300 doses of European supply chain pregabalin, arresting a suspect and disrupting illegal shipments between Greece and France⁶².

Pregabalin has also been reported to have been discovered in falsified forms and, similar to other falsified medicines, was found to contain dangerous ingredients. In a case reported in Northern Ireland, a death was attributed to falsified pregabalin⁶³.

Many of the incidents reported above also include references to the illicit trading of **tramadol** as a product in its own right or as an adulterating ingredient within other falsified controlled medicines. The scale of illicit trading reporting of tramadol would indicate that the product transcends high to low and middle income countries and may therefore be considered a global risk.

Examples include of incidents involving tramadol include:

• Nigerian authorities reporting a seizure of 35 million tramadol tablets. In another incident within the same media report, 59,106 tramadol tablets were seized by authorities⁶⁴.

⁵⁶ <u>https://www.bbc.co.uk/news/articles/c3ejky0dy47o</u>

⁵⁷ <u>https://www.nhs.uk/medicines/pregabalin/</u>

⁵⁸ https://www.youtube.com/watch?v=8fc8sXWopBs

⁵⁹<u>https://www.penington.org.au/wp-content/uploads/2023/08/PEN_Annual-Overdose-Report-2023_FINAL.pdf</u>

⁶⁰ https://www.bbc.co.uk/news/uk-northern-ireland-66579996

⁶¹ <u>https://www.francebleu.fr/infos/faits-divers-justice/les-gendarmes-de-clermont-ferrand-demantelent-un-reseau-de-trafic-de-medicaments-contenant-de-la-pregabaline-4537607</u>

⁶²<u>https://www.devdiscourse.com/article/law-order/3164134-international-smuggling-ring-busted-pregabalin-drugs-seized</u>

⁶³https://www.sundayworld.com/crime/courts/mum-whose-son-died-after-taking-deadly-extra-strongdrugs-says-dealers-are-murderers/a1653469269.html

⁶⁴<u>https://www.ndlea.gov.ng/news/ndlea-intercepts-3-trailer-loads-of-opioids-seizes-35million-pills-344000-codeine-bottles</u>

- A US FDA health alert reported falsified Adderall containing tramadol rather than the correct active pharmaceutical ingredient⁶⁵.
- In the UK 1.5 million tramadol tablets were reported as being stolen from a lorry⁶⁶.
- Again, in the UK, a pharmacist was jailed for 12 months for diverting around 800,000 tablets, including tramadol, onto the illicit market⁶⁷.

The UNODC has previously reported on the scale of illict trading of tramadol in West Africa⁶⁸. As highlighted previously, the Global Initiative Against Transnational Organised Crime (European Drugs Trends – issue 1)⁶⁹ identified ilicit trading of tramadol on Dutch retail channels on Telegram where the average price for a tramadol tablet was \in 1.41 and in Germany the average price per tablet for tramadol for \in 0.71.

The reported average prices of prescription opioids on illicit trading sites is highly significant and likely to be a contributing factor to what may be described as a thriving illegal trade and significant risk to healthcare systems.

Products such as **fentanyl and ketamine** are also subject to multiple reports of their illicit trading as products in their own right or as ingredients within other falsified medicines. Deaths from their usage have also been reported in the media, on occasions involving known public figures⁷⁰.

Examples of cases involving these products:

- The arrest by Filipinno authorities of an individual in possession of 14 grammes of ketamine who had been supplying the product via an online facility⁷¹.
- There are many US-based reports of incidents involving both fentanyl and ketamin. Such a case resulted in an individual being imprisoned for 12 years after involvement in the trafficking of suboxone, ketamine, fentanyl tablets, and medical grade fentanyl⁷².
- Law enforcement activity retrieving 0.5kg of ketamine⁷³.
- Seizure of large quantity of ketamine by Hong Kong customs⁷⁴.
- Seizure of 2.6kg of ketamine by Canadian customs⁷⁵.

⁶⁵<u>https://www.safemedicines.org/wp-content/uploads/Press-Announcements-_-FDA-warns-</u> <u>consumers-about-counterfeit-version-of-Tevas-Adderall.pdf</u>

⁶⁶ https://www.bbc.co.uk/news/uk-england-43419503

⁶⁷ https://www.bbc.co.uk/news/uk-england-birmingham-56255803

⁶⁸ https://www.unodc.org/conig/uploads/documents/Tramadol_Trafficking_in_West_Africa.pdf

⁶⁹ <u>https://globalinitiative.net/wp-content/uploads/2024/12/Observatory-of-Organized-Crime-in-Europe-European-Drug-Trends-Monitor-Issue-1-GI-TOC-December-2024.v3.pdf</u>

⁷⁰ https://www.bbc.co.uk/news/articles/c89wgv989250

⁷¹ <u>https://www.pna.gov.ph/articles/1229862</u>

⁷²https://www.justice.gov/usao-wdwa/pr/renton-washington-man-sentenced-11-years-prison-hugestash-guns-and-drugs

⁷³ https://x.com/mpshackney/status/1879845108033732789?s=12

⁷⁴ https://x.com/hongkongmarket/status/1875919684643779048?s=12

⁷⁵ https://x.com/canborder/status/1879936799981572298?s=12

- A report released by the US DEA highlighted that 6 out of 10 falsified controlled medicines laced with fentanyl contained a potentially lethal dose⁷⁶.
- The WCO Illicit Trade report highlighted 5456kg of ketamine seized in 2023 and increase from 3724kg in 2022. Additionally, highlighting Germany, Belgium and the Netherlands as significant hubs⁷⁷. The WCO report also highlighted fentanyl as a worrying threat.
- Seizure by Canadian law enforcement of 9kg of fentanyl⁷⁸.

2.3.2. Medicines Overview

Whilst this paper has detailed the significant illicit trade and falsification of controlled medicines, medicines that are not subject to enhanced controls are also the subject of legal acts. Medicines that may be grouped as lifestyle products, including weight loss, sexual health and skin treatment, i.e. botox, are also subject to diversion and falsification. Such products are typically in demand across the globe.

a) Erectile Dysfunction Medication: Viagra®/ Cialis® (medicine)

As highlighted within a previously mentioned RCMP report⁷⁹, Viagra® and Cialis® are amongst a number of medicines assessed as most likely to be falsified. In a recent case in the USA, two brothers pleaded guilty to selling \$35 million worth of falsified Viagra®⁸⁰. Reports of authorities responding to incidents related to falsified Viagra® are longstanding. The sophistication of the manufacture of falsified Viagra® was highlighted in an incident reported in 2016. Polish police conducted searches of a factory reported as the 'world's largest' fake Viagra® factory worth at least £4million⁸¹. The outcome of the searches resulted in:

- around 100,000 falsified tablets for erectile dysfunction and steroids seized.
- manufacturing equipment worth £860k found.
- Polish police made 14 arrests in connection with the illegal factory.

Falsified versions of Viagra® have also been identified by authorities as containing dangerous volumes of ingredients or active pharmaceutical ingredients (API). In a case reported in the UK, Chinese-manufactured falsified Viagra® was found to contain such large quantities of API as to pose a risk to men with cardiac conditions⁸². Similar reports have been publicised in relation to falsified Cialis®⁸³.

⁷⁶ <u>https://www.dea.gov/alert/dea-laboratory-testing-reveals-6-out-10-fentanyl-laced-fake-prescription-pills-now-contain</u>

 ⁷⁷https://www.wcoomd.org/-/media/wco/public/global/pdf/topics/enforcement-andcompliance/activities-and-programmes/illicit-trade-report/itr_2023_en.pdf?db=web
 ⁷⁸https://brandon.ca/news/media-releases/update-to-fentanyl-seizure-from-january-25th-2024?highlight=WyJmZW50YW55bCJd

⁷⁹ https://www.rcmp-grc.gc.ca/en/qc/increase-the-consumption-counterfeit-drugs

⁸⁰ <u>https://www.justice.gov/usao-sc/pr/summerville-brothers-plead-guilty-selling-35m-worth-counterfeit-viagra</u>

⁸¹<u>https://www.dailymail.co.uk/news/article-3801640/They-expect-stiff-sentence-Polish-police-raid-world-s-largest-fake-Viagra-factory-worth-4million.html</u>

⁸² https://www.dailyrecord.co.uk/news/uk-world-news/fake-viagra-is-death-risk-956558

⁸³ https://www.cbc.ca/news/health/fake-anti-impotence-drug-found-in-ontario-1.1111020?ref=rss

Unlike some of the controlled medicines previously discussed, falsified versions of Viagra® and Cialis® have been identified across the globe and not limited to western HICs.

- In Israel in 2007, two importers of falsified Viagra® tablets received prison sentences, in separate cases. Of note, this was the first time that imprisonment had been awarded for offences of importing falsified Viagra®⁸⁴.
- In China, a man was jailed for selling 14,030 falsified Viagra® tablets on the internet⁸⁵.
- In South Korea two brothers were charged with making and selling around 1.5 million falsified erectile dysfunction tablets between September 2020 and March 2024⁸⁶.
- A notice issued by US Customs and Border Protection highlighted the seizure of falsified Viagra® tablets made at the US border by officials⁸⁷.
- In the UK, a criminal enterprise planned to supply falsified erectile dysfunction tablets. An investigation identified a plan to produce falsified Cialis® with a street value of £1.6m (\$2.6m). Christiaan Winkel, Yuly Sandoval-Moro and Safa Issoto Ba Sedi, pleaded guilty to conspiracy to defraud. Winkel was sentenced to 40 months imprisonment; Ba Sedi was sentenced to 21 months imprisonment, and Sadoval-Mora to eight months imprisonment, which was suspended⁸⁸.

Whilst no open-source incidents of reported illicit diversion of either product have been identified there have been multiple global reports of seizures and prosecutions relating to falsified versions of Viagra®, Cialis®, and other generic erectile dysfunction products.

b) Antibiotics and anti-imflamatories (medicine)

Antibiotics and anti-imflamatories have been the subject of seizures by authorities and on occassions in large quantities.

Authorities in the Domininican Republic reported seizing 800,000 doses of falsified medicines including amoxicillin and Ibuprofen. No further details were provided other than three persons were arrested and face potentail preventative detention⁸⁹.

In Senegal during an intensification operation, as reported in the media, record seizures of falsified antibiotics and anti-inflamatories were made by authorities⁹⁰ and in India 30,000 falsified antibiotic tablets were seized during enforcement activity⁹¹.

⁸⁴ https://www.safemedicines.org/2007/05/importers-of-fake-viagra-sent-to-jail.html

⁸⁵ https://www.safemedicines.org/2008/04/man-in-shanghai-jailed-for-selling-fake-viagra.html

⁸⁶ https://www.koreatimes.co.kr/www/nation/2024/06/113_376525.html

⁸⁷<u>https://www.safemedicines.org/wp-content/uploads/2023/08/Silenafil-seizure-Newark-NJ-Aug-2023.jpeg</u>

⁸⁸<u>https://www.securingindustry.com/pharmaceuticals/uk-gang-jailed-for-counterfeit-medicines-plot/s40/a869/</u>

⁸⁹<u>https://dominicantoday.com/dr/local/2024/11/04/authorities-dismantle-counterfeit-medicine-operation/</u>

⁹⁰ <u>https://www.senenews.com/en/senegal/senegal-record-seizure-of-counterfeit-medicines-and-drugs-</u> worth-523-million-cfa-3854.html

⁹¹ <u>https://timesofindia.indiatimes.com/city/hyderabad/crackdown-on-spurious-antibiotics-major-racket-uncovered-in-hyderabad/articleshow/115575235.cms</u>

c) Semaglutide Products (Medicine)

Semaglutide products have in recent years been the subject of emerging reports of falsified versions being seized by authorities in many jurisidictions. Concerns regarding the risk posed by falsified Ozempic® resulted in the issuing of a medical product alert by the World Health Organisation⁹² following the identification of the same falsified batch in Brazil, UK and USA. Subsequent to this alert the same falsified batch was identified in a range of other countries, including Mexico, Iraq, Lebanon and Serbia⁹³. Other products of a similar nature, i.e. Saxenda (Liraglutide), have also been the subject of such reporting.

Falsified versions of Ozempic® have been identified as being supplied in illegal markets resulting in multiple investigations. In a media article in the USA, checks by border authorities identified illicit trading of the product⁹⁴. The UK's MHRA have also released information in 2023 highlighting the seizure of 369 falsified Ozempic® pens⁹⁵.

Risks to public health have been highlighted in numerous jurisdisctions, for example in Austria where several people were hospitalised following the use of suspected falsified Ozempic® reported to contain insulin⁹⁶. This report suggested the products were obtained outside of medical supervision, however, the UK's MHRA reported that pre-filled pens falsely labelled as Ozempic® were identified at two licensed UK wholesalers. Following investigation, the MHRA confirmed that the products were brought into the UK from legitimate suppliers in Austria and Germany⁹⁷. Any breach of the regulated supply chain by falsified products is a critical issue with potential risk to public health and wider public confidence in the health care system. Additionally, Australia's TGA has issued a public health alert following the reporting of an adverse event and the identification of falsified versions of Ozempic pens, purchased outside of the regulated supply chain, that were discovered to contain insulin⁹⁸.

Another investigation by Austrian authorities resulted in criminal charges against two men accused of selling falsified versions of Ozempic® which caused adverse harm to three women. It was reported that the suspects acted as traders and sold 225 falsified Ozempic® pens at 205 euros each. Similar to other cases previously referred to forensic analysis identified the pens containing insulin instead of semaglutide⁹⁹.

⁹²<u>https://www.who.int/news/item/19-06-2024-medical-product-alert-n-2-2024--falsified-ozempic-</u>(semaglutide)

⁹³ https://www.safemedicines.org/2024/09/sept-9-2024.html

⁹⁴<u>https://myfox28columbus.com/news/local/ohio-border-patrol-us-customs-cbp-bust-millions-in-</u> counterfeit-goods-merchandise-jewelry-fake-botox-knock-off-ozempic

⁹⁵ <u>https://www.gov.uk/government/news/mhra-warns-of-unsafe-fake-weight-loss-pens</u>

⁹⁶ https://www.bbc.co.uk/news/world-europe-67217729

⁹⁷<u>https://www.gov.uk/government/news/falsified-ozempic-semaglutide-pens-identified-at-two-wholesalers-in-the-uk</u>

⁹⁸<u>https://www.tga.gov.au/news/safety-alerts/counterfeit-ozempic-pens-detected-and-adverse-event-reported</u>

⁹⁹<u>https://www.reuters.com/business/healthcare-pharmaceuticals/sellers-fake-ozempic-face-charges-austrian-court-2024-07-09/</u>

Insulin found within falsified versions of Ozempic® is also a medicine, however, currently there are no identified reports of the illicit diversion or seizures of falsified versions of the insulin. This raises the question of the source of the insulin used in the falsified version of Ozempic®.

The emergence of online celebrity influencers promoting dietary products¹⁰⁰ is likely to increase the threats of both illicit diversion, diversion into markets for which the product was not manufactured or approved and the provision of falsified versions of these products outside of medical supervision.

d) Botox® (Medicine)

There have been extensive reports by authorities of falsified versions of Botox® being identified. In 2022, the WHO issued a medical product alert following the detection of five falsified batches in Jordan (May 2022), Türkiye (May 2022), Kuwait (June 2022), United Kingdom (June 2022), and Poland (July 2022)¹⁰¹. Reports emerge on a regular basis, in April 2024 the US Food and Drug Administration reported falsified versions of Botox® had been identified in numerous US States¹⁰². Further coverage within US media highlighted that a total of 19 women from nine states — Colorado, Florida, Illinois, Kentucky, Nebraska, New Jersey, New York, Tennessee, and Washington had reported subsequent adverse reactions¹⁰³.

Issues related to Botox® have been reported across the globe. In a media report entitled "More Than Half of China's Botox Believed to Be Fake or Smuggled", the scale of falsified versions of Botox® is made clear. In Thailand, authorities searched two locations identifying a production site for the manufacture of falsified Botox®. This followed an investigation into online groups. Police seized over 26,000 items reported at a value of 10 million bhat and a non-specfied number of suspects were arrested¹⁰⁴.

Europol's Operation Shield targets the trafficking of counterfeit and misused medicines and illicit doping substances¹⁰⁵. Related activity in 2023 resulted in Greek authorities dismantling a criminal network that had been trafficking unauthorised pharmaceuticals and medical devices since 2019 including falsified Botox®. Seized products were imported via couriers or transported from Türkiye and Poland.

e) Antimalarials

In regions of the globe where malaria remains a health concern, the diversion and falsification of antimalarial medicines has been reported. An example of this resulted in a public health

 ¹⁰¹ https://www.who.int/news/item/19-08-2022-medical-product-alert-n-4-2022-falsified-dysport
 ¹⁰² https://www.fda.gov/drugs/drug-safety-and-availability/counterfeit-version-botox-found-multiplestates?utm_medium=email&utm_source=govdelivery

¹⁰⁰ <u>https://www.bbc.co.uk/news/health-47090374</u>

¹⁰³https://edition.cnn.com/2024/04/16/health/counterfeit-botox-what-to-

know/index.html#:~:text=The%20US%20Food%20and%20Drug%20Administration%20is%20warning ,states%2C%20putting%20the%20safety%20of%20consumers%20at%20risk.

¹⁰⁴ https://world.thaipbs.or.th/detail/multiple-raids-on-fake-botox-suppliers/503

¹⁰⁵ <u>https://www.europol.europa.eu/media-press/newsroom/news/fake-medicines-worth-eur-64-million-eu-markets</u>

warning issued by Nigerian authorities following the identification of falsified antimalarials¹⁰⁶. Similar issues exist in relation to the theft and diversion of antimalarials, an example of which in Zambia resulted in enforcement action¹⁰⁷.

3.4. Overview: New Psychoactive and other substances

A New Psychoactive Substance (NPS) is a substance of abuse that is not controlled under International Drug Control Conventions. As a result, the status of NPS can therefore vary widely from country to country¹⁰⁸. Both Ireland¹⁰⁹ and the UK¹¹⁰, for example, have enacted specific legislation banning certain activities in relation to NPS such as advertising, sell, supply and export, whilst in other countries there is no such legislation.

The emergence of NPS is a relatively recent phenomenon, thus the use of the term 'new.' NPS present a significant threat to public health and as described in this report, NPS can span illicit markets from its use as a substance of abuse in its own right to being an ingredient within falsified versions of genuine medicines¹¹¹. As a result, NPS can present risks to a broader section of society, to non-medical users of prescription controlled medicines and to those purchasing NPS as a substance/product in its own right.

NPS are often described as legal highs or designer drugs¹¹² and are hugely varied in nature, including:

- Khat.
- Synthetic cannabinoids.
- Lysergamides, a product that can provide hallucinogenic systems.

The following NPS have been widely reported by authorities.

3.4.1. Captagon

Captagon was first legitimately manufactured in 1961 as an alternative to amphetamine and methamphetamine which was used at the time to treat ailments such as narcolepsy, fatigue, and the behavioural disorder "minimal brain dysfunction". The vision in developing Captagon was a product that was a milder version of these medicines. But by the 1980's the U.S. government declared it a controlled substance with no accepted medical use. Manufacturing of the drug has in general been banned since the 1980's¹¹³. In 1986, Captagon (fenetylline) was included in Schedule II of the United Nations Convention on Psychotropic Substances 1971, and at that point most countries discontinued the use of Captagon. It was subsequently

 ¹⁰⁶https://nafdac.gov.ng/public-alert-no-049-2024-sales-and-distribution-of-confirmed-counterfeitpaludex-artemether-lumefantrine-tablets-80mg-480mg-and-suspension-20mg-120mg/
 ¹⁰⁷https://www.zambiamonitor.com/authorities-crackdown-on-illegal-pharmacies-arrest-20-forpossession-of-govt-procured-drugs/

¹⁰⁸ https://www.unodc.org/LSS/Page/NPS

¹⁰⁹ https://www.irishstatutebook.ie/eli/2010/act/22/enacted/en/html

¹¹⁰ https://www.legislation.gov.uk/ukpga/2016/2/contents;

¹¹¹<u>https://www.irs.gov/compliance/criminal-investigation/florida-man-and-woman-sentenced-for-conspiracy-to-sell-counterfeit-drugs-on-dark-web</u>

¹¹² https://www.bbc.co.uk/news/uk-32857256

¹¹³ https://www.drugs.com/lifestyle/captagon-available-2961377/

reported by the International Narcotics Control Board in 2011 that no country had produced it since 2009¹¹⁴.

In more recent times, Captagon has gained the nickname "the jihadists' drug". Numerous media reports have discussed the potential link between terrorist attacks and Captagon. For example, following terrorist attacks in Israel in October 2023 it was subsequently reported that Captagon pills were found in the pockets of terrorists who died in the incident¹¹⁵. Reports suggest it keeps users awake for long periods of time, dulls pain and creates a sense of euphoria¹¹⁶.

Large seizures of Captagon have been made by authorities:

- Malaysian authorities seized 94.8 million tablets valued at US\$1.2 billion¹¹⁷
- UAE authorities seized 86 million Captagon tablets valued at US\$ 1 billion¹¹⁸
- Jordanian authorities seized 6 million Captagon tablets¹¹⁹
- Other seizures have been made by European authorities, e.g. Netherlands and Greece¹²⁰

The scale of seizures made by authorities has now been placed into context following recent events in Syria where Captagon manufacturing sites have been identified. In an article entitled *"Sacks of chemicals, plastic fruit ... and millions of pills: inside a Damascus Captagon factory"*¹²¹ the scale of the manufacturing has been laid bare and may go some way to explaining the huge volume of tablets seized by authorities in the Middle East region and beyond.

3.4.2. Nitazene

Nitazenes were initially developed in the 1950s as analgesics, however, they were found to be so potent that they were never approved or marketed as medicines. Since the late 2000s they have been identified within illegal drug supplies in the USA, UK and other European countries¹²².

Nitazenes are a class of strong, synthetic opioids, similar to fentanyl, and as highlighted previously in this paper, are mixed with other products to create what may be intended to be

¹¹⁴ <u>https://www.aljazeera.com/news/2023/5/9/what-is-captagon-the-addictive-drug-mass-produced-in-syria</u>

¹¹⁵ <u>https://www.jpost.com/health-and-wellness/article-769250</u>

¹¹⁶<u>https://www.newsweek.com/drugs-captagon-islamic-state-jihad-war-amphetamines-saudi-arabia-608233#:~:text=Captagon%20is%20one%20of%20the%20brand%20names%20for,lungs%20and%20is%20used%20to%20treat%20breathing%20problems.</u>

¹¹⁷ https://www.occrp.org/en/news/malaysia-seizes-drugs-worth-12-billion

¹¹⁸ https://www.bbc.co.uk/news/world-middle-east-66810832

¹¹⁹ https://www.bbc.co.uk/news/world-middle-east-64091223

¹²⁰ https://maritime-executive.com/article/greek-officials-score-record-setting-amphetamine-bust

¹²¹https://www.theguardian.com/world/2024/dec/16/syrias-captagon-trade-inside-a-damascusamphetamine-factory

¹²² https://pharmaceutical-journal.com/article/feature/everything-you-need-to-know-about-nitazenes

a falsified version of controlled medicines. It is reported that some nitazenes are up to 43 times stronger than fentanyl¹²³.

The threats posed by nitazenes are emerging as a wider global issue. The director-general of the UK's National Crime Agency highlighted 284 overdose deaths in the UK linked to nitazene¹²⁴. The adulteration of falsified products presented as prescription-controlled medicines, such as diazepam, was a contributing factor to reported fatal outcomes.

In Sweden, police issued a public warning (Dangerous drug sold in fake packaging in Karlstad¹²⁵) to its citizens following the identification of a falsified version of a controlled medicine adulterated with a nitazene called "metonitazene". This product was available within local illicit markets. The alert highlighted the dangers of the falsified product and the potentially fatal consequences following ingestion.

In Australia, for example, seizures have been made of falsified controlled medicines containing nitazenes resulting in public safety messaging "Public health warning: Severe opioid overdoses from nitazenes in fake oxycodone"¹²⁶. Whilst other reported incidents in Australia have highlighted the illicit supply of the actual raw product of nitazenes¹²⁷.

3.4.3. Etizolam

Etizolam's approval as a licensed medicinal product is limited to a small number of countries, however, as a novel benzodiazepine¹²⁸ it is subject to extensive reporting both as an ingredient of falsified controlled medicines and as a separate psychoactive substance. It was patented in 1972 and, where authorised for therapeutic use, has been prescribed for anxiety and sleep disorder, e.g. Italy¹²⁹. It is a psychoactive drug which is a controlled substance in some countries¹³⁰.

As highlighted previously, etizolam has been identified as a substance used in the production of falsified, mainly controlled medicines, such as Xanax® and diazepam¹³¹.

¹²³<u>https://www.forbes.com/sites/ariannajohnson/2024/01/02/what-to-know-about-nitazenes-rare-but-emerging-opioids-more-potent-than-fentanyl/</u>

¹²⁴ <u>https://www.manchestereveningnews.co.uk/news/greater-manchester-news/almost-300-die-super-strength-29746610</u>

¹²⁵<u>https://polisen.se/aktuellt/pressmeddelanden/2024/augusti/farlig-drog-saljs-i-falsk-forpackning-i-karlstad/</u>

¹²⁶ <u>https://www.health.nsw.gov.au/news/Pages/20241126_03.aspx</u>

¹²⁷ <u>https://www.afp.gov.au/news-centre/media-release/nt-man-charged-over-potent-opioid-mail-import-prompts-warning</u>

¹²⁸<u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/8</u> 81969/ACMD_report_-

a review of the evidence of use and harms of novel benzodiazepines.pdf

 ¹²⁹ https://www.aifa.gov.it/documents/20142/2594020/AIFA Rapporto OsMed 2023 EN.pdf
 ¹³⁰ https://www.gov.uk/government/publications/controlled-drugs-list--2/list-of-most-commonlyencountered-drugs-currently-controlled-under-the-misuse-of-drugs-legislation

¹³¹<u>https://www.irs.gov/compliance/criminal-investigation/florida-man-and-woman-sentenced-for-</u>conspiracy-to-sell-counterfeit-drugs-on-dark-web

Public health warnings regarding falsified controlled medicines identified as containing etizolam have been issued in a number of jurisdictions¹³² ¹³³.

Etizolam has also been reported being illicitly manufactured as etizolam tablets in their own right. In 2019 UK police raided an industrial unit and discovered machinery and raw materials to produce thousands of etizolam tablets. It was assessed that chemicals seized could have made up to £2.5m worth of the drugs. In November 2024 five defendants were convicted and received suspended prison sentences¹³⁴.

In June 2020, UK authorities raided a pill factory in Kent and seized the 28 million Etizolam tablets. Following a criminal prosecution in 2024 four defendants were sentenced to imprisonment of 20, 7, 6 and 4 years, respectively¹³⁵.

In another case, this time in the USA, a California man pleaded guilty to selling etizolam over the internet. The defendant purchased etizolam from suppliers in China, imported it into the USA and sold the etizolam with false labelling stating that the products were sold "For Research Purposes Only" and "Not for Human Consumption". Based on an analysis of bank and cryptocurrency records, the defendant and co-conspirator conducted gross sales of over \$550,000 of etizolam through the internet¹³⁶.

3.4.4. Xylazine

Xylazine is a powerful animal tranquilizer. Although it is not intended for human use, it is a common ingredient within illicit controlled medicines, particularly within the USA¹³⁷. As a substance of abuse, it is becoming more widely known beyond the USA. Reported incidents include the adulteration of illicit e-cigarettes with the substance¹³⁸.

As a new substance of abuse xylazine's status varies significantly across the world. For example, in the USA it is not a controlled substance¹³⁹, whilst in the UK it is¹⁴⁰.

Reports have emerged where xylazine has been identified as an ingredient within falsified medicines. Such a case in the USA involved falsified oxycodone¹⁴¹. The risk of either using xylazine directly or as an ingredient within a falsified medicine are significant with, for example, the UK reporting its first death linked to xylazine in 2023¹⁴².

¹³⁴ <u>https://www.bbc.co.uk/news/articles/ceqxyv8e5n4o</u>

undercover-agent-gets-6-years-in-prison/

¹³²<u>https://www.southlanarkshire.gov.uk/info/200228/health_and_medical_information/1892/community_addiction_recovery_services_cares/2</u>

¹³³ https://www.health.nsw.gov.au/news/Pages/20191212_02.aspx

¹³⁵<u>https://www.nationalcrimeagency.gov.uk/news/operation-venetic-international-drug-trafficker-sentenced-to-20-years</u>

¹³⁶ <u>https://www.justice.gov/usao-ma/pr/california-man-pleads-guilty-selling-illegal-depressant-etizolam-over-internet</u>

¹³⁷ <u>https://www.poison.org/articles/what-is-xylazine</u>

¹³⁸ https://www.bbc.co.uk/news/health-68760301

¹³⁹ <u>https://www.deadiversion.usdoj.gov/drug_chem_info/Xylazine.pdf</u>

¹⁴⁰ <u>https://www.gov.uk/government/news/britain-takes-decisive-action-to-ban-zombie-drug-xylazine</u>
¹⁴¹ <u>https://www.orlando-news.com/2024/11/19/orlando-man-who-sold-fake-fentanyl-pills-gun-to-</u>

¹⁴² https://www.bbc.co.uk/news/health-65696801

4. DISCUSSION

It is asserted from global reporting that the threat of the illicit diversion and falsification of medicines remains a significant challenge to authorities. The majority of the open-source reports identified during this research, subject to the limitations previously highlighted, have related to incidents involving controlled medicines, those medicines are the subject of enhanced controls. This is consistent with incidents of both illicit diversion and the falsification of controlled medicines. It is also noted that reports of both illicit diversion and falsification of controlled medicines are mainly within HICs.

Falsified tablets are typically reported as being detected within illicit markets presenting as legitimate prescription-controlled medicines such as oxycodone, and benzodiazepines, e.g. diazepam. The development of illicit production and related risks was highlighted in published research¹⁴³. This research commented on the introduction of falsified tablets containing synthetic opioids "changing the overdose landscape by placing a wider population at risk of unintentional exposure, especially since a large proportion of those who misuse prescription drugs such as benzodiazepines and opioids, obtain them from nonmedical sources".

Falsified versions of controlled medicines forensically analysed by authorities were almost always accompanied with the identification of dangerous undisclosed ingredients, such as nitazenes¹⁴⁴. The risk to public health is evidenced through serious adverse reactions and, on occasions, fatal outcomes¹⁴⁵.

Illicit diversion involving legitimately manufactured controlled medicines typically involved highly organised criminal enterprises diverting large volumes of products from the supply chains of HICs to other HICs involving significant financial gain¹⁴⁶. Again, reports of diversion incidents mostly involved controlled medicines.

In 2016 the UK's Advisory Council on the Misuse of Drugs (ACMD) in a report produced for the UK government on the diversion and illicit supply of medicines¹⁴⁷ concluded:

- The most prevalent diverted medicines were opioids and benzodiazepines.
- The Internet is an increasing illicit source of medicines with many unregistered online pharmacies supplying prescriptions and medicines unethically.
- There is a common perception that prevalence of diversion and illicit supply of medicines is increasing.
- Quantifying the extent of the issue is difficult owing to a lack of suitable monitoring systems.

¹⁴³ Bruzelius, E., Palamar, J. J., Fitzgerald, N. D., Cottler, L. B., Carr, T. C., Martins, S.S. (2024). Law enforcement fentanyl seizures and overdose mortality in US counties, 2013–2020. Drug and Alcohol Dependence, vol 262.

¹⁴⁴ https://www.instagram.com/p/C_r_JiGus-7/?img_index=1

¹⁴⁵ https://www.bbc.co.uk/news/uk-wales-58262827

¹⁴⁶<u>https://cbsp.policja.pl/cbs/aktualnosci/215101,Leki-zawierajace-substancje-psychotropowe-wysylano-min-do-USA-rozbity-gang.html</u>

¹⁴⁷https://assets.publishing.service.gov.uk/media/5a81733ced915d74e33fe464/Meds_reportfinal_report_15_December_LU_2_.pdf

These findings and related issues are as relevant today in 2025 as when they were initially produced by the authors in 2016.

The requirement by criminal entities to continue to access, advertise and sell falsified and regulated supply chain controlled medicines highlights three issues worthy of further discussion:

4.1. The role that regulated supply chain losses and thefts may play in illicit diversion:

- Whilst losses within the supply chain that go unexplained maybe perceived as low volume incidents involving small amounts of controlled medicines, a recent investigatory media report highlighted the 'unexplained loss' of \$4 million worth of controlled medicines from a pharmacy¹⁴⁸. The report went on to analyse the scale and nature of medicines subject of such reporting over a six-year period within the Canadian market. The top eight products in terms of volume amounted to losses of nearly 10 million doses being 'lost' within the regulated supply chain over the period analysed. Of further concern was that seven of the top eight were controlled medicines and subject to enhanced controls relating to manufacture, distribution, storage, and prescribing. One of the remaining medicines, whilst not classified as a controlled medicine, is known for its propensity for abuse in the manufacture of illicit methamphetamine. The article reinforced the potential for these losses to be leaked into the illegal market.
- Research that has been conducted, including findings by Dugato and Sidoti (2023), has highlighted a growing trend in the organised theft of medicines. Their European study additionally revealed that in 2020, 72% of pharmaceutical-related crimes reported by the Pharmaceutical Security Institute (PSI) involved the illicit diversion of pharmaceuticals¹⁴⁹.
- Reported incidents of theft are a thread that runs throughout this report.

4.2. Does illicit diversion increase the risk of subsequent falsification?

The identification of falsified controlled medicines packaged within primary and secondary packaging is not an overly unusual occurrence. However, the seizure of falsified products, packaged in the primary and secondary packaging of a different product that was subject of previous high volume illicit diversion is a worrying development. Does access to illicitly diverted medicines increase the opportunity for subsequent falsification of the product? One of the priorities for authorities responding to incidents of illicit diversion is to resecure the supply chain. An unintended consequence of securing the supply chain may lead to increased risks of the production of falsified versions to meet non-medical usage demand.

¹⁴⁸ <u>https://www.cbc.ca/news/canada/unexplained-losses-prescription-drugs-1.7247602</u>

¹⁴⁹ Dugato, M., & Sidoti, C. (2023). The Organised Theft of Medicines: A Study of the Methods for Stealing and Reselling Medicines and Medical Devices in the EU and Beyond. European Journal on Criminal Policy and Research.

4.3. The use of the internet to facilitate the supply of both falsified and illicitly diverted medicines

It is reported that Organised Crime Groups (OGGs) and individual enterprises acting with illegal purposes are increasingly engaging in crimes involving medical products¹⁵⁰. They exploit technological advances, such as e-commerce platforms, and interconnected fast parcel services, to facilitate their illegal activities. Additionally, described in many of the case examples used within this report is the use of the expanding capabilities of the internet to facilitate illegal trading of falsified and illicitly diverted medicines.

The use of the internet to enable the illegal trading of medicines is not a new phenomenon and has been widely recognised by others¹⁵¹, however, it is clearly evidenced within reports from authorities that it continues at a pace and a key facilitator for criminal activity.

The use of the internet and social media as a whole continues to increase worldwide, as highlighted by the UNODC publication 'Use of the dark web and social media for drug supply.' It is assessed that two thirds of the global population have access to the Internet (66 per cent) with more than half accessing social media (59 per cent)¹⁵². It is a reasonable assumption to conclude these numbers will only increase.

In seeking to combat this enabler, since its commencement in 2008, Interpol's Operation Pangea has focused on the illegal sale online of counterfeit and illicit medicines¹⁵³.

Recent activity as part of Operation Pangea XVI reported the following results¹⁵⁴

- Participation of 89 countries
- Seizure of pharmaceuticals to the value of \$7million
- Closure of 1,300 websites
- The instigation of 325 new investigations

The illicit trading of pharmaceutical products is also recognised as a key threat by the World Customs Organisation (WCO). Global action by customs agencies led to the following seizures of pharmaceuticals during 2023¹⁵⁵:

- 4,434 separate seizures
- 158 million pieces
- 338 tonnes in weight

 ¹⁵⁰ <u>https://www.ilgiorno.it/cronaca/traffico-ossicodone-stati-uniti-arresti-03e118d4</u>
 ¹⁵¹ https://www.researchgate.net/publication/355887493 ILLEGAL INTERNET PHARMACIES AS A

THREAT_TO_PUBLIC_HEALTH_IN_EUROPE

 ¹⁵² <u>https://www.unodc.org/res/WDR-2023/WDR23_B3_CH7_darkweb.pdf</u>
 ¹⁵³<u>https://www.interpol.int/News-and-Events/News/2019/Operation-Pangea-shining-a-light-on-pharmaceutical-crime</u>

¹⁵⁴https://www.interpol.int/News-and-Events/News/2023/Global-illicit-medicines-targeted-by-INTERPOL-operation

¹⁵⁵<u>https://www.wcoomd.org/-/media/wco/public/global/pdf/topics/enforcement-and-compliance/activities-and-programmes/illicit-trade-report/itr_2023_en.pdf?db=web</u>

Evidence from Operation Pangea, WCO and many of the case studies described in this report, provide further proof of the scale of the current challenges of illegal online sale, supply, and illicit trading of all medicines. This is further supported by a recent publication by the Global Initiative Against Transnational Crime (European Drugs Trends Monitor issue 1) highlighting the online transnational illicit trading in controlled medicines such as oxycodone and tramadol¹⁵⁶. The report went on to further recognise the challenge of trafficking in prescription opioids as key trends:

- KEY TREND 2: While there is almost no explicit demand for fentanyl and nitazenes, trafficking in prescription opioids is an emerging phenomenon.
- KEY TREND 3: Trafficking in prescription opioids may herald highly potent illegal synthetic opioids.

A recent case reported in the USA highlights the scale of the threat from online availability of illicit controlled medicines presented as legitimate medicines being supplied by legitimate health service providers:

*"U.S. Attorney Announces Charges Against 18 Defendants In Scheme To Manufacture And Distribute Millions Of Deadly Counterfeit Pharmaceuticals Through Fake Online Pharmacies"*¹⁵⁷.

The case reported was transnational in its scope with defendants located in the United States, Dominican Republic, and India, and involved actors in these countries in a scheme to advertise, sell, manufacture, and ship millions of falsified tablets disguised as legitimate pharmaceuticals. The falsified tablets were purchased by tens of thousands of victims from illicit online suppliers purporting to be genuine pharmacies. The tablets supplied contained fentanyl, para-fluorofentanyl, and methamphetamine and were presented as genuine prescription medicines, including oxycodone, hydrocodone, Adderall®, and Xanax®, among others.

The impact of this transnational criminality, trafficking, resulted in the death from narcotic poisoning of at least nine victims who purchased falsified tablets, including a 45-year-old army veteran who thought they were purchasing genuine oxycodone.

¹⁵⁶ <u>https://globalinitiative.net/wp-content/uploads/2024/12/Observatory-of-Organized-Crime-in-Europe-European-Drug-Trends-Monitor-Issue-1-GI-TOC-December-2024.v3.pdf</u>
 ¹⁵⁷<u>https://www.justice.gov/usao-sdny/pr/us-attorney-announces-charges-against-18-defendants-scheme-manufacture-and-distribute</u>

5. CONCLUSION

This paper has set out to describe some of the key threats and challenges faced by authorities in preventing, detecting, and responding to reports of the illicit diversion of authorised medicines and the identification of falsified versions of legitimate medicines. The information and data used within this report is based upon open-source reporting from publicly available information. The challenges for States include protecting the patient and wider public health whilst ensuring the security of the regulated supply chain both in terms of preventing falsified medicines entering the supply chain but also in preventing medicines being intentionally removed from the supply chain and diverted either into the illicit market or being placed on the legitimate markets for medicines in countries which were not the intended recipients and are not authorised there.

In researching this paper, a key challenge has continued to present itself:

"How do we achieve a more detailed understanding of the scale and detail of the problem to inform evidence-based strategic and tactical responses?"

The recently published WHO report '*Global Surveillance and Monitoring System for substandard and falsified medical products: Activity report August 2017–December 2021*¹⁵⁸ made a number of recommendations. It is noted that of particular relevance to the conclusion of this report was the recommendation to:

• strengthen national and international recording systems

In concluding this report, it is proposed that to enhance the foundations required for the development of informed responses three key areas may require exploration and further consideration:

- Data There is a limited availability of data/ comprehensive data set.
- Research Limited research of the topic and sub-topics has been conducted.
- Analysis As a result of the previous two issues there has been a paucity of detailed analysis to inform focus and direction.

¹⁵⁸ <u>https://www.who.int/publications/i/item/9789240097513</u>

Appendix :

Links to publicly available reports used to compile this paper

1. General discussion

- Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health. (2011). Council of Europe Treaty Series- No. 211. https://rm.coe.int/168008482f
- https://www.who.int/health-topics/drugs-psychoactive#tab=tab_1
- https://cbsp.policja.pl/cbs/aktualnosci/215101,Leki-zawierajace-substancjepsychotropowe-wysylano-min-do-USA-rozbity-gang.html
- https://www.rcmp-grc.gc.ca/en/qc/increase-the-consumption-counterfeit-drugs
- https://www.dea.gov/factsheets/fake-prescription-pills
- https://www.consilium.europa.eu/en/policies/opioids-drugs-heroin/
- https://www.euda.europa.eu/sites/default/files/pdf/31629_en.pdf?571720
- https://globalinitiative.net/wp-content/uploads/2024/12/Observatory-of-Organized-Crime-in-Europe-European-Drug-Trends-Monitor-Issue-1-GI-TOC-December-2024.v3.pdf
- Bruzelius, E., Palamar, J. J., Fitzgerald, N. D., Cottler, L. B., Carr, T. C., Martins, S.S. (2024). Law enforcement fentanyl seizures and overdose mortality in US counties, 2013–2020. Drug and Alcohol Dependence, vol 262.
- https://www.instagram.com/p/C_r_JiGus-7/?img_index=1
- https://www.bbc.co.uk/news/uk-wales-58262827
- https://www.cbc.ca/news/canada/unexplained-losses-prescription-drugs-1.7247602
- Dugato, M., & Sidoti, C. (2023). The Organised Theft of Medicines: A Study of the Methods for Stealing and Reselling Medicines and Medical Devices in the EU and Beyond. European Journal on Criminal Policy and Research.
- https://www.ilgiorno.it/cronaca/traffico-ossicodone-stati-uniti-arresti-03e118d4
- https://www.unodc.org/res/WDR-2023/WDR23_B3_CH7_darkweb.pdf
- https://www.interpol.int/News-and-Events/News/2019/Operation-Pangea-shining-alight-on-pharmaceutical-crime
- https://www.interpol.int/News-and-Events/News/2023/Global-illicit-medicinestargeted-by-INTERPOL-operation
- https://www.wcoomd.org/-/media/wco/public/global/pdf/topics/enforcement-and-compliance/activities-and-programmes/illicit-trade-report/itr_2023_en.pdf?db=web
- https://globalinitiative.net/wp-content/uploads/2024/12/Observatory-of-Organized-Crime-in-Europe-European-Drug-Trends-Monitor-Issue-1-GI-TOC-December-2024.v3.pdf
- https://www.justice.gov/usao-sdny/pr/us-attorney-announces-charges-against-18defendants-scheme-manufacture-and-distribute
- https://www.who.int/publications/i/item/9789240097513
- https://assets.publishing.service.gov.uk/media/5a81733ced915d74e33fe464/Meds_re port-_final_report_15_December_LU__2_.pdf

2. Controlled medicines

Oxycontin®/ oxycodone

- https://www.ilgiorno.it/cronaca/traffico-ossicodone-stati-uniti-arresti-03e118d4
- https://www.fanpage.it/milano/spacciava-ossicodone-e-morfine-online-arrestato-un-ragazzo-di-22-anni/
- https://www.france24.com/en/live-news/20210519-italy-police-dismantle-drug-ring-sending-opioids-to-us
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