United Nations
Office on Drugs and Crime

Minimizing the risk of diversion of pharmaceuticals containing controlled substances from the regulated supply chain

A practitioner's handbook for effective operational practice

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UNITED NATIONS
Vienna, 2025

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This publication has not been formally edited.

Publishing production: Publishing Section, United Nations Office at Vienna.

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Acknowledgements

The United Nations Office on Drugs and Crime (UNODC) would like to acknowledge the individuals and organizations listed below for their invaluable contribution to the development of the handbook on minimizing the risk of diversion of pharmaceuticals containing controlled substances from the regulated supply chain. Their collaborative efforts made this publication possible.

First and foremost, we extend our sincere appreciation to Mark Jackson, UNODC international consultant and the primary author of this handbook. His dedication, deep subject matter expertise and thoughtful approach to content development were central to shaping the handbook into a practical and comprehensive resource.

We would also like to express our sincere appreciation to the numerous individuals from international and regional organizations who contributed their time, knowledge and perspectives to this handbook. Their insights enriched the content and helped ensure its global relevance and applicability. We acknowledge the important input of experts from the following organizations, listed in alphabetical order by organization: Anthony Bakenga Kapeta (African Union); Deborah Maestre (CICAD); Kevin Bigler, Terrence Boos and Kurt Dittmer (DEA); Eric Krakauer (Harvard Medical School); Tania Pastrana Uruena (IAHPC); Stefano Berterame (INCB); Hugo Bonar (MEDICRIME Committee, Council of Europe); Susan Winckler (Reagan-Udall Foundation); Rebeca Sabou (UNIDO); Xavier Tomsej (USAID); Naseem Hudroge, Rutendo Kuwana and Dilkushi Poovendran (WHO). Particular thanks go to those who provided comments: Elin Maria Bergsten, Heloisa Broggiato, Scott Burris, Michael Deats, Marco Dugato, Tomasz Lisiewski, Kimberley New, Timothy Mackey, Brandon Maser, Luke Overmire, Frederico Pasqualini, Brian Sekayombya and Zahi Muhammad Sulaiman. Their diverse expertise and collective commitment to improving access to controlled medicines while preventing diversion were instrumental in the development of this publication.

We gratefully acknowledge the contributions of the experts who took part in the TCM meeting: Ruzana Abdullah, Almehdi ali Almehdi Akari, Saleh Aljafran, Adah Adede Allotey-Pappoe, Anunchai Assawamakin, Marie Chantale Assouan, Aicha Bammou, Erick Alfonso Palacios Barillas, Vasco Bettencourt, Saed Bilbaisi, Syed Saadat Ali Bokhari, Yacine Boumrah,

Sophie Boyson, Marina Chilikina, Maria Cristina Baracaldo Cortes, Quexuan Cui, Yang Daravuth, Jonatan Jaime López Díaz, Māra Dišlere, Luis Mauricio Estrella Endara, Catarina Ekenäs, Espen Freng, Bogdan Dan Gheorghe, Nina Grøntved, Serdar Hakberdiyev, Alejandra Beatriz Merino Herrera, Jesus Herrera, Jeong Ho, Souleymane Mamoudou Idrissa, Andrej Janžič, Elsa Jara, Mariana Jitaru, Job Kandie, Cheong Mun Khiong, Ana Kintsurashvili, Stephen Knight, Hajah Rosnita Haji Lakat, Børge Myrlund Larsen, Hien Le, Maria Grazia Leone, Katrīna Lukša, Stanislav Lungu, Zablon K. Lyatuu, Ziliwa Peter Machbya, Clarette Matlab, Reezwanah Bibi Mawlaboccus, Omar Farooq Mohammed, Paola Edith Hernández Montenegro, Nisreen Mohamed Ahmed Nassr, Diana Nevzorova, Tomas Nilsson, Ilona Ościłowska, Dominic Korsah Otchere, Soutongo Sita Sandrine Kabre Ouedraogo, Dace Persa, Karol Pomarański, Galina Pyshnik, Korapin Na Ranong, Lakpriya Viraj Rohan Ratnayake, Fakhrour Razy, Gabriel Rebalderia, Milver Rojas, Shahrizal bin Saad, Mohamed Sengab, Rocco Signorile, Thiago Brasil Silverio, Renata de Morais Souza, Viorica Stepanova- Belcencova, Maruska Strappatelli, Viengsamay Syleuxay, Emilia Szuba, Johanna Alexandra Jaimes Valero, Viengxay Vansilalom, Ashley R. Verenga, Steve Weber, Ranjith Wickramasinghe, Adnan Yassin and Ardeshir Zahedi. Their participation and insights enriched the development of this handbook and helped ensure its practical relevance and applicability across diverse contexts.

The United Nations Office on Drugs and Crime played a central role in the development of this handbook. A special thanks are due to Justice Tettey, Chief, Drugs, Laboratory and Scientific Services Branch; Giovanna Campello, Chief, Prevention Treatment and Rehabilitation Section, and Tatiana Jehl, Drug Policy Officer, Drugs, Laboratory and Scientific Services Branch, whose leadership, support, and guidance was instrumental in advancing the development of this handbook. We also extend our deep appreciation to the colleagues of the Prevention, Treatment and Rehabilitation Section managing the programme of work on ensuring access to controlled substances for medical and scientific purposes while preventing diversion and non-medical use: Laleh Ashrafi Kakhki, Yinse Chen, Lauren Pearl Fleming, Nataliya Graninger, Qihui Gui, Julia Langmuir, Ava Liang, Yusheng Mu, Zoe O'Dwyer, Miranda Parra, Umunnakwe Princewill, Elizabeth Saenz Miranda, Charalampos Salivaras, Christine Toavs, whose dedication and hard work were critical to finalizing and coordinating the handbook.

Executive summary

The Single Convention on Narcotic Drugs of 1961, as amended by the 1972 protocol, "recognizes that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering, and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes". Also, the Convention on Psychotropic Substances of 1971 "recognizes that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted". In practice, pharmaceuticals with an identified or emergent clinical application whose active ingredients are listed under the 1961 or the 1971 drug conventions (herewith in this document "controlled medicines") are indispensable for the relief of pain and the treatment of mental and neurological conditions, as well as substance use disorders. Thus, adequate accessibility when needed is essential. Major policy documents of the Commission on Narcotic Drugs (CND), including the 2016 United Nations General Assembly Special Session outcome document and CND resolution 63/3, promote awareness-raising, education and training, as part of a comprehensive approach to ensure availability of and access to internationally controlled substances for medical and scientific use.

Appropriately prescribed controlled medicines are critical for a variety of indications in adults and children including pain relief, surgical anaesthesia and the treatment of various mental, neurological and substance use disorders. Millions of patients suffer from pain due to lack of access to essential controlled medicines. There are, however, significant geographical variations in accessing controlled medicines for identified clinical needs.[1] Barriers such as those related to overly restrictive legislation, regulatory systems, healthcare systems, affordability, the training of healthcare professionals, education, awareness-raising, estimates, assessments and reporting, supply chain gaps, prescriber fear of legal repercussions, prescriber fear of non-medical use and diversion, among other factors, all contribute to global inequities in access to controlled medicines.[2] It is thus vital to identify the contributors to the main barriers that prevail at national level to ensure that controlled medicines are accessible to patients in need.

Ensuring safe access to controlled medicines requires the prevention and detection of, and response to, their diversion. The diversion of medicines containing substances under international control is a significant global health problem, leading to illegal trafficking, increasing non-medical use and lethal overdoses, and a higher burden on healthcare systems. As the goal of preventing diversion should not interfere with or limit the legitimate use of controlled substances for medical use, the international drug conventions convey a dual obligation of ensuring the balance between the availability and the control of substances. UNODC contributes to the efforts to enable access to substances under international control for medical and scientific purposes, while preventing their diversion and non-medical use, by servicing the international policymaking processes in the Commission on Narcotic Drugs (CND), as well as providing technical assistance to Member States that request it.

[1] World Health Organization. (2023). "Left behind in pain". https://www.who.int/publications/i/item/9789240075269.

[2] INCB (2022). Supplement to the annual report of the Board for 2022 on the availability of internationally controlled substances.

In recent years, there have been two contrasting opioid-related crises. The first has been an epidemic of opioid-use disorders, opioid overdoses and deaths related to opioid over-prescription or diversion and widespread availability of falsified controlled medicines adulterated with fentanyl or other substances, mainly within high income countries. The second crisis is the insufficient access to opioids such as morphine, mostly in low- and middle-income countries, resulting in millions of people enduring avoidable pain.[3,4] In a recent report, the World Health Organization emphasizes that morphine is an essential medicine used for relieving acute or chronic, moderate or severe pain, triggered by causes such as cancer, cardiovascular disease, major trauma or surgery. Morphine is the gold standard for pain relief, having been listed in the WHO Model List of Essential Medicines since 1977. Nevertheless, access to high quality pharmaceutically manufactured morphine is limited by various obstacles, including supply chain coordination issues, insufficient physical, financial and skilled human resources, weak governance and misconceptions about pain and opioid use.

Another recently released WHO report describes the factors contributing to the lack of access to controlled medicines for the treatment of neurological disorders.[5] Similarly, the International Narcotics Control Board (INCB) highlights the vital role that medicines containing controlled substances, i.e. controlled medicines, such as buprenorphine, diazepam, lorazepam, midazolam and phenobarbital, play in the management of mental illness and neurological disorders. However, millions of people, especially in low- and middle-income countries, still lack access to these crucial medications. In these regions, mental health services are often limited and difficult to reach, resulting in inadequate availability of prescribed treatments. Simultaneously, there is growing concern about the over-prescription, self-medication and non-medical use of medicines containing substances under international control (narcotics and psychotropics) often in high income countries. The unsupervised, long-term use of these substances, particularly among vulnerable groups or when combined with other drugs, can potentially lead to dependence and harm.[6] Such demand can be one of the drivers that leads to the diversion of controlled medicines from the regulated supply chain.[7]

This handbook constitutes an essential component among the UNODC tools that support Member States in addressing the impact of the diversion of controlled medicines on the availability of and access to substances under international control for medical and scientific purposes, while preventing diversion and non-medical use. In addition to two sets of training materials on the issue of diversion, one aimed at relevant stakeholders and the other at healthcare professionals this handbook adds to the already existing tools with which UNODC provides technical assistance to Member States.

[3] https://repository.gheli.harvard.edu/repository/11818/.

[4] www.who.int/publications/i/item/9789240075269.

[5] World Health Organization. (2024). *Improving access to medicines for neurological disorders*. https://www.who.int/publications/i/item/9789240097377.

[6] Thomas, K.H., Dalili, M.N., Cheng, H., Dawson, S., Donnelly, N., Higgins, J.P.T., and Hickman, M. (2024). "Prevalence of problematic pharmaceutical opioid use in patients with chronic non-cancer pain: A systematic review and meta-analysis." *Addiction*, vol 119, issue 11.

[7] www.gov.scot/publications/evidence-review-current-trends-benzodiazepine-use-scotland/.

Glossary of terms and abbreviations

ACMD	Advisory Council on the misuse of drugs (United Kingdom)
AIFA	Agenzia Italiana del Farmaco (medicines agency of Italy)
Controlled medicines	For the purposes of this document, controlled medicines refer to pharmaceuticals with an identified or emergent clinical application whose active principles are listed under the 1961 or 1971 drug conventions.
CDC	Centres for Disease Control and prevention (United States of America)
CND	Commission on Narcotic Drugs
Covert human intelligence source	An informer providing information, paid or unpaid, and staff from authorities working undercover or as a test purchase operative.
Covert surveillance	Covertly monitoring, observing or listening to persons, their movements, conversations or other activities or communications as part of an investigation or intelligence gathering initiative.
Diversion	For the purposes of this document, diversion refers to the unsanctioned intentional supply of controlled medicines from legal sources to the illegal drug market, or to a user, or to a stakeholder within the regulated supply chain, for whom the drugs were not intended.
DISM	Diversion and illicit supply of medicines
ECOSOC	Economic and Social Council
EUDA	European Drugs Agency
Essential medicines	Medicines on the WHO Model List selected with due regard to disease prevalence and public health relevance, evidence of clinical efficacy and safety and comparative cost effectiveness.
Falsified medicines	Medical products that deliberately/fraudulently misrepresent their identity, composition or source
FIP	International Pharmaceutical Federation

GDP	Good distribution practice
GSDP	Good storage and distribution practice
GPP	Good pharmacy practice
INCB	International Narcotics Control Board
INTERPOL	International organization that facilitates worldwide police cooperation and crime control.
MEDICRIME Convention	Council of Europe international treaty against counterfeit medical products and similar crimes involving threats to public health
Operation Pangea	Coordinated by INTERPOL, Operation Pangea is an international effort to disrupt the online sale of counterfeit and illicit health products.
PSI	Pharmaceutical Security Institute
Substances under international control	Refers to substances listed in the schedules (for the 1961 and 1971 Conventions) and tables (for the 1988 Convention) which are annexed to these conventions.
Test purchase	A covert attempt by authorities to purchase a medicine (or any other suspected illegal commodity) online or from a specific location or person as part of an ongoing investigation or intelligence gathering initiative.
TGA	Therapeutic Goods Administration (Australia)
Third-party risk management (TPRM)	Process that identifies, assesses and mitigates risks with outsourcing of tasks to third-party vendors or service providers.
UNODC	United Nations Office on Drugs and Crime
WCO	World Customs Organization
WDA	Wholesaler distribution authorization
WHO	World Health Organization

1. Framing the challenge: ensuring access, preventing diversion – scope and overview

1.1 International legal framework

Under the international drug conventions, States Parties are required to ensure that mandatory control measures are applied to substances and precursors listed in the schedules of the Single Convention on Narcotic Drugs of 1961, the schedules of the Convention on Psychotropic Substances of 1971 and the tables of the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.[1] The main mandatory requirements to States Parties include:

- Institutional infrastructure for domestic and international drug control
- Regulation of trade
- Demand reduction
- Drug-related criminal justice
- International justice sector cooperation

States Parties are required to establish a system of control covering all stages of the supply chain for controlled substances. This includes licensing entities involved in manufacture, distribution, import, export and dispensing; maintaining records and inspections; and reporting annual statistics to the International Narcotics Control Board (INCB). INCB is the repository of global data on the availability of narcotic drugs and psychotropic substances for pain management and mental health treatment.[2] These data are reported by Member States as established by the two of the conventions mentioned above, the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances of 1971, and subsequent resolutions of the United Nations Economic and Social Council (ECOSOC) and CND. Countries report statistics on their consumption, cultivation and production of narcotic drugs and psychotropic substances for the past calendar year, and their estimated needs for such substances for the next calendar year. This information is verified based on the

[1] www.unodc.org/unodc/en/commissions/CND/Mandate_Functions/index.html.
[2] www.incb.org/incb/en/publications/annual-reports/annual-report.html.

trade data reported by all trading countries on a quarterly basis. These mechanisms aim at preventing the diversion of controlled substances under international control.

To meet these obligations, States Parties are required to designate a national authority responsible for overseeing the cultivation, manufacture, distribution, import and export of controlled medicines. This authority must also furnish annual estimates and statistical data to INCB and establish regulatory systems to ensure oversight across all stages of the supply chain.

Furthermore, States Parties must enforce a licensing requirement for all relevant stakeholders and establish and maintain systems for the compliance inspection of regulated persons and enterprises. These compliance mechanisms support the integrity of the supply chain and contribute to ensuring that the regulatory obligations are met in a consistent and accountable manner.[3]

1.2 The role of the World Health Organization

Within the United Nations international drug control system, the World Health Organization (WHO) contributes to the implementation of the conventions by providing expertise in several key areas. Under the Convention on Psychotropic Substances of 1971, Member States are encouraged to base prevention, treatment and rehabilitation measures on WHO recommendations and to take WHO guidance into account when establishing labelling requirements for psychotropic substances. While WHO does not directly regulate access or diversion control, it plays an important supporting role by providing normative guidance, technical tools and capacity-building resources to help Member States develop balanced policies that improve access to and availability of controlled medicines, while preventing diversion and non-medical use.[4]

As an additional effort to ensure access to medicines, WHO has identified essential medicines that are of priority to the health needs of all populations. Medicines included in the WHO Model List are selected based on disease prevalence and public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness. Though not all controlled medicines are included in the WHO list of essential medicines, many (such as morphine in immediate-release oral and injectable preparations) are opiate based and included in section two of the Model List. Under international law, the international drug conventions create a legal obligation for States Parties to ensure the availability of controlled substances for medical purposes. Therefore, the inclusion of such controlled medicines in the WHO Model List reinforces the importance of the availability of and the access to controlled substances that are listed in the schedules of the international drug conventions.

[3] Links to all the international drug control conventions can be found here: www.unodc.org/unodc/en/commissions/CND/Mandate_Functions/conventions.html?utm.

[4] 1971 Convention on Psychotropic Substances: www.incb.org/documents/Psychotropics/conventions/Commentary_on_the_Convention_1971.pdf.

1.3 Access versus diversion

Ensuring and supporting adequate access to controlled medicines as part of identified clinical need while safeguarding a secure regulated supply chain that prevents diversion is crucial. Such medicines are intended, through appropriate, responsible and safe prescribing, to always be available in functioning health systems, in appropriate dosage forms, of assured quality, and at prices individuals and health systems can afford.

The availability of and access to controlled substances for medical and scientific purposes are therefore important factors in ensuring patients receive appropriate healthcare. Many generic essential controlled medicines, including those containing morphine, diazepam, oxycodone and hydromorphone have been legally available for prescription to patients for many decades. Morphine was in fact first marketed around two centuries ago.

The aim of this handbook is to contribute to the increased safe availability of and access to controlled medicines for patients in need across the globe, by addressing one of the key barriers, namely fear of diversion, through effectively contributing to minimizing the risk of diversion of pharmaceuticals containing controlled substances from the regulated supply chain.

For the purposes of this document and clarity for the reader, the following terminology will be used:

- "Controlled medicines" will be utilized to refer to pharmaceuticals with an identified or emergent clinical application whose active ingredients are listed under the 1961 or 1971 drug conventions.
- "Diversion" refers to the unsanctioned intentional supply of controlled medicines from legal sources to the illegal drug market, or to a user, or to a stakeholder within the regulated supply chain, for whom the drugs were not intended.

The handbook provides insight into common methods utilized to divert controlled medicines, as well as a menu of tactical and strategic options and good practice to minimize the risk of diversion of controlled medicines within a "Prevent, Detect and Respond" model (see Figure 1). The United States Government Accountability Office has produced the following helpful visual describing some of the many diversion challenges that this handbook seeks to address.

While relevant to the topic, some issues are not discussed in this document to maintain the focus on an already complex thematic. These include: the prevention of diversion of controlled substances for scientific purposes; indications about legislation needed to prevent diversion of controlled medicines; and the prevention of diversion to a user for whom the drugs were not intended. Preventing the non-medical use of controlled medicines is outside the scope of this document. Information on this issue can be found in the UNODC discussion paper on "The non-medical use of prescription drugs – Policy direction issues".[5]

[5] www.unodc.org/documents/drug-prevention-and-treatment/nonmedical-use-prescription-drugs.pdf.

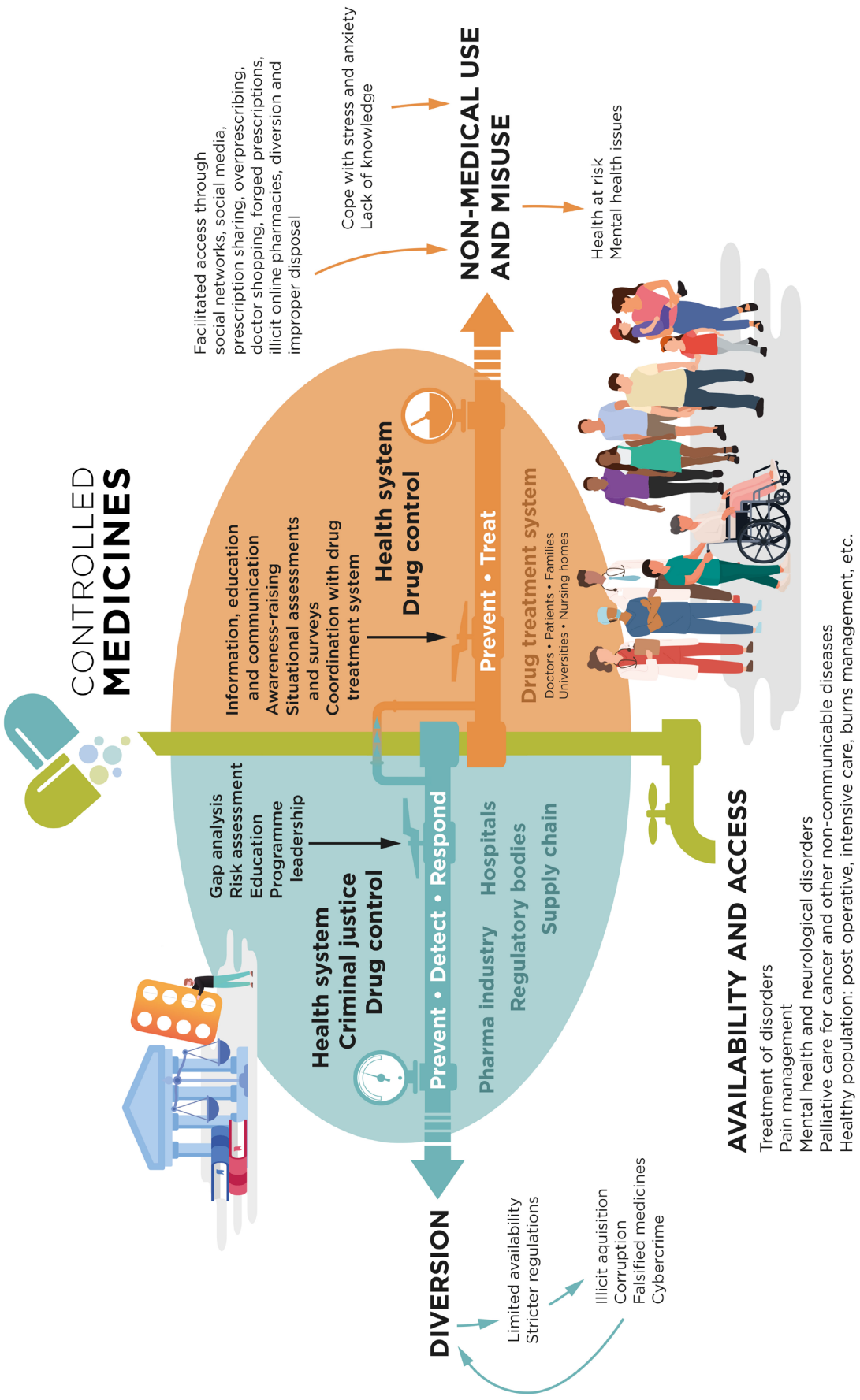

Figure 1. The interconnectedness between availability, access, diversion, non-medical use and misuse

1.4 The problem of diversion

Medicines are not ordinary consumer products and activities including their pre-clinical testing, clinical trials, manufacture, importation, exportation, wholesale distribution, ongoing safety, advertising and supply are subject to strict regulatory control in line with local jurisdictions and are enforceable by law. Moreover, medicines which contain internationally controlled active pharmaceutical ingredients, i.e. controlled medicines, are subject to enhanced regulatory controls that can be stricter. The diversion of controlled medicines from the regulated supply chain to illegal markets constitutes a form of pharmaceutical crime.

Understanding the scale of diversion is challenging, due to:

- Limited research into the global, regional and national phenomenon of diversion of controlled medicines
- A lack of a consistent, commonly recognized definition and understanding of diversion
- The absence of consolidated data

To support an effective regulatory system for all medicines in each country WHO works to develop internationally recognized norms, standards and guidelines for medicine quality, safety and efficacy.[6] This is supported at country level by WHO assisting countries to develop and implement effective medicines regulation systems that promote and protect public health by ensuring certain standards, including the following, to safeguard that:

- Medicines are of the required quality, safety and efficacy.
- Medicines are appropriately manufactured, stored, distributed, dispensed and destroyed.
- Illegal manufacturing and trade are detected and adequately sanctioned.
- Unjustified regulatory work does not hinder access to medicines.

Within this wider regulatory framework that applies to all medicines, supply chain security is relevant as medicines are transported from the point of manufacture, through distributors and wholesalers, to hospitals and pharmacies, and finally to the point of patient dispensing. For medicines containing controlled substances in their formulation, ensuring the security of the regulated supply chain, including appropriate storage, is paramount. This is critical in order for patients to receive medicines of the appropriate quality, efficacy and safety while ensuring the security of controlled medicines.

Recent research has highlighted a growing trend in the organized theft of medicines and a European study additionally revealed that in 2020, 72 per cent of pharmaceutical-related crimes reported by the Pharmaceutical Security Institute (PSI) involved the diversion of pharmaceuticals.[7] PSI is a not-for-profit organization, which, among other functions, collects

[6] www.who.int/europe/activities/regulating-medical-products/regulating-medical-products#:~:text=At%20the%20global%20level%2C%20WHO%20works%20to%20develop,of%20their%20own%20specific%20regulatory%20environment%20and%20needs.

[7] Dugato, M., and 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*.

and analyses intelligence on reported pharmaceutical crime. Its membership is made up of major international pharmaceutical manufacturers.[8]

1.5 Scope and limitations of the handbook

Most of the research into the diversion of controlled medicines has been geographically focused on North America. For example, in their 2010 study, entitled "The Relationship Between Source of Diversion and Prescription Drug Misuse, Abuse, and Dependence", Ford and Lacerenza examined how individuals obtain prescription drugs (source of diversion) and how they misuse these drugs (i.e., frequency, use and dependence).[9]

Incidents involving the diversion of controlled medicines from the regulated supply chain and into illegal markets are frequently reported in the media.[10] These reports often highlight the large-scale, wholesale diversion of supply chain medicines, describing extensive international networks of sophisticated criminal enterprises. The diversion of controlled medicines can be a transnational crime that impacts not only the supply chain and healthcare provision in the source country but also in the destination country to which the controlled medicines are trafficked and subsequently sold within the illegal market for non-medical use.

The 2016 Advisory Council on the Misuse of Drugs (ACMD) report, commissioned by the Government of the United Kingdom, on the diversion and illicit supply of medicines[11] concluded that:

- 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 the 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.

The use of the Internet and social media continues to increase worldwide, as highlighted in a chapter in the *World Drug Report 2023* entitled "Use of the dark web and social media for drug supply". It is estimated 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).[12]

Controlled medicines diverted out of the regulated supply chain will mainly be sold within the illegal market for non-medical use. Those engaged in this illegal activity require methods to advertise and sell their products. One growing area where pharmaceuticals are sold illegally is online through websites, marketplaces and social media sites. Increasing access to and use of the Internet is leading to increasing sales, supply and purchasing of controlled medicines

[8] www.psi-inc.org/.

[9] Ford, J.A., and Lacerenza, C. (2010). "The Relationship Between Source of Diversion and Prescription Drug Misuse, Abuse, and Dependence". *Substance Use & Misuse*, vol 46, 2011, issue 6.

[10] https://cbsp.policja.pl/cbs/aktualnosci/215101,Leki-zawierajace-substancje-psychotropowe-wysylano-min-do-USA-rozbity-gang.html (in Polish).

[11] https://assets.publishing.service.gov.uk/media/5a81733ced915d74e33fe464/Meds_report-_final_report_15_December_LU__2_.pdf.

[12] www.unodc.org/res/WDR-2023/WDR23_B3_CH7_darkweb.pdf.

and other medicines through online sources.[13] The use of the Internet as an enabling tool in facilitating a range of pharmaceutical crimes is recognized by other guidance, for example, the UNODC publication *Combating falsified medical product-related crime: A guide to good legislative practices*.[14] The diversion of controlled medicines is no different, as the Internet often facilitates the transnational trafficking of the products.[15]

While not specific to controlled medicines, an indicator of the scale of illegal online sales of pharmaceuticals in general is regularly reported as part of the INTERPOL annual initiative, Operation Pangea. Since its commencement in 2008, Operation Pangea has focused on the "illegal sale online of counterfeit and illicit medicines".[16]

Recent activity as part of Operation Pangea XVI reported the following results:[17]

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

The breadth of countries participating, and the volume of medicines seized during a short period of action, highlights the scale of the challenge, which continues to grow with increasing global access to Internet services, multiple methods of payment and the proliferation of fast parcel services.

The illegal trading in pharmaceutical products is recognized as a key threat by the World Customs Organization (WCO). Global action by customs agencies led to the following seizures of pharmaceuticals during 2023:

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

The process for collating this data is carried out on a voluntary basis by members of WCO. In this report, 75 of the 186 members of WCO submitted details of seizures across all illegal trade commodities.

Evidence provided by both the INTERPOL Operation Pangea and WCO highlights the scale of the challenge of the illegal online sale, supply and illegal trading of all medicines, including unlicensed, substandard and falsified medicines, and medicines diverted from the regulated supply chain, including controlled medicines. Recent cases have highlighted the size and scale of the illegal online sale of supply chain-controlled medicines.[18] The estimated continued growth in e-commerce indicates that illegal sale of pharmaceuticals online is only likely to increase, including diverted controlled medicines.

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[13] www.justice.gov/usao-sdny/pr/incognito-market-owner-arrested-operating-one-largest-illegal-narcotics-marketplaces.

[14] www.unodc.org/documents/treaties/publications/19-00741_Guide_Falsified_Medical_Products_ebook.pdf.

[15] https://www.interpol.int/en/Crimes/Illicit-goods/Pharmaceutical-crime-operations

[16] www.interpol.int/News-and-Events/News/2019/Operation-Pangea-shining-a-light-on-pharmaceutical-crime.

[17] www.interpol.int/News-and-Events/News/2023/Global-illicit-medicines-targeted-by-INTERPOL-operation.

[18] https://cbsp.policja.pl/cbs/aktualnosci/215101,Leki-zawierajace-substancje-psychotropowe-wysylano-min-do-USA-rozbity-gang.html (in Polish).

2. Understanding the problem

2.1 What is diversion?

While the term "diversion" lacks a universally accepted definition, the international drug conventions require States Parties to criminalize under domestic law the following intentional acts when contrary to the provisions of the conventions (i.e. not for medical or scientific use): the production, manufacture, extraction, preparation, offering, offering for sale, distribution, sale, delivery (on any terms), brokerage, dispatch, dispatch in transit, transport, importation or exportation of any narcotic drug or psychotropic substance in contravention of the 1961 Convention, the 1961 Convention as amended, or the 1971 Convention.

Although the conventions do not provide a formal definition of "diversion", they contain clear obligations for States Parties to prevent and penalize the unauthorized movement of controlled medicines. The 1961 Convention requires States Parties to limit these to medical and scientific purposes, and to criminalize any activities that fall outside that scope. As ratified treaties, the international drug control conventions provide a binding global framework that underpins the mandate of UNODC and stands in contrast to the more limited regional application of instruments such as the MEDICRIME Convention.

The absence of a standardized definition of pharmaceutical diversion hinders a comprehensive assessment of the problem's scope, complicating efforts to address it effectively. The MEDICRIME Convention,[19] a treaty developed to define a set of common and legally binding definitions for the falsification of medical products and other similar crimes, does not explicitly define diversion and instead encompasses the issue within article 8 of the Convention as a "similar crime".[20]

As defined within the MEDICRIME Convention, article 8 defines similar crimes involving threats to public health as follows:

> Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, in so far as such an activity is not covered by Articles 5, 6 and 7:

[19] www.coe.int/medicrime.

[20] https://rm.coe.int/medicrime-10-questions-and-answers-eng/168096d6bc.

A: the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of:

i. medicinal products without authorisation where such authorisation is required under the domestic law of the Party: or

ii. medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party.

B: the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party.[21]

INTERPOL has adopted a broad description of pharmaceutical crime to include many differing elements. This is defined as "the manufacture, trade and distribution of fake, stolen or illicit medicines and medical devices. It encompasses the counterfeiting and falsification of medical products, their packaging and associated documentation, as well as theft, fraud, illicit diversion, smuggling, trafficking, and money laundering".[22]

Although it does not provide a definition of the diversion of medicines, the WHO Member State Mechanism on Substandard and Falsified Medical Products clearly defines a falsified medicine as "medical products that deliberately and fraudulently misrepresent their identity, composition or source".[23]

Medicines that have been illegally removed from the regulated supply chain and subsequently reinserted back into the regulated supply chain will, following the WHO definition, be falsified medicines. The source of these medicines will have been deliberately and fraudulently misrepresented to allow access to and distribution within the regulated supply chain. Medicines that have illegally been removed from the supply chain cannot be certain that they maintain requisite quality standards and will therefore pose significant safety risks to prescribed patients.

In this context, and as mentioned above, for the purposes of this document the following definition of diversion has been adopted:

> The unsanctioned intentional supply of controlled medicines from legal sources to the illegal drug market, or to a user, or to a stakeholder within the regulated supply chain, for whom the drugs were not intended.

2.2 Methods of diversion

The following are examples of reported high-volume diversion incidents describing how controlled medicines have exited the regulated supply chain and entered the illegal market, where criminal entities, operating without licences, profit substantially by selling them for non-medical purposes (see Figure 2).

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[21] https://rm.coe.int/168008482f.

[22] www.interpol.int/News-and-Events/News/2013/INTERPOL-and-pharmaceutical-industry-launch-global-initiative-to-combat-fake-medicines.

[23] World Health Organization. (2022). "The WHO Member State Mechanism on Substandard and Falsified Medical Products", p. 6, update 2022. www.who.int/publications/i/item/WHO-MHP-RPQ-REG-2022.01.

Diversion of licensed pharmaceutical purchases to illegal markets

Reports of rogue actors making excessive purchases of medicines from within the supply chain are prevalent across various jurisdictions.[24] Once these products exit the legitimate supply chain, they are often sold on illegal markets, frequently via online platforms to individuals outside of medical supervision. Given the abundance of controlled medicines in the supply chains of high-income countries, such activities are more likely to occur in these contexts. Subsequent resale typically targets buyers for non-medical purposes within similar high-income countries, maximizing criminal profit.

An example of such excessive purchasing was reported in a 2024 court prosecution involving the illegal diversion of benzodiazepines and illustrates this trend: a community pharmacy in the United Kingdom procured 55 million doses of various medicines, including 47 million doses of diazepam, in just over four years. The offences of diverting and selling the controlled medicines outside of the regulated supply chain were described in court as on an "industrial scale". To contextualize the scale of this diversion, in 2014, only 5 million doses of diazepam were legally dispensed across the entirety of England.[25]

Illegally obtaining controlled medicines using fraudulent prescriptions

Acting as the frontline for dispensing controlled medicines to patients based on legitimate prescriptions from doctors, pharmacies are susceptible to fraudulent activities. These may involve stolen prescriptions, fraudulently obtained prescriptions or other scams aimed at illegally acquiring controlled medicines, often in significant quantities.[26] Such illegal activities are typically identified through changes in:

- Frequency of individuals presenting prescriptions
- Significant increases in supply chain demand at pharmacy level
- Overall volume of prescriptions
- Dosage strength of the products required to be dispensed, i.e. a change to purely high-strength products

Moreover, media-led research in the United Kingdom has underscored the vulnerability of community pharmacies. The study highlighted a significant number of crimes reported to police forces within these establishments, including crimes of violence. Between 2019 and 2020, pharmacies reported 15,858 crimes, encompassing theft and violence stemming from disputes over medication. It is plausible that the reported figures represent only a fraction of the actual problem, as many incidents are likely to go unreported to the authorities.

[24] https://cbsp.policja.pl/cbs/aktualnosci/215101,Leki-zawierajace-substancje-psychotropowe-wysylano-min-do-USA-rozbity-gang.html (in Polish).

[25] www.gov.uk/government/news/pharmacists-who-illegally-supplied-more-than-55-million-doses-of-controlled-drugs-sentenced.

[26] www.gov.uk/government/news/pharmacists-jailed-for-a-combined-total-of-57-months-for-illegal-supply-of-prescription-medicines.

International research into the attitudes of victims and repeat victims towards the police (van Dijk 2001[27]) concluded that:

- Less than 40 per cent of more serious offences are reported to the police.
- Reporting is particularly low in most developing countries.

Theft or losses within the supply chain

Product theft remains an ongoing concern across all business supply chains. In May 2024 alone, the Transport Asset Protection Association (TAPA) for the Europe, Middle East and Africa region recorded 140 incidents involving a range of differing commodities valued at $1,372,438.[28] The specific vulnerabilities of pharmaceuticals were emphasized in a collaborative article by several pharmaceutical manufacturers. A key finding highlighted that cargo theft poses a critical risk that pharmaceutical manufacturers and their associated supply chains must address, as it could result in unauthorized product diversion, adulteration and counterfeiting, directly impacting patient safety.[29]

The risk of theft, however, spans the entirety of the supply chain. Research into the theft of medicines across European Union countries (Dugato and Sidoti, 2023)[30] identified three key phases in the supply chain where thefts are most likely to occur:

- Warehouse and production sites
- Transportation
- Hospitals, healthcare and pharmacies

Research by Fan et al in 2019 into diversion, theft and losses in hospitals identified a range of issues, including the significant finding that 79 per cent of incidents within Canadian hospitals involving controlled medicine losses were simply categorized as “unexplained losses”. The research assessed that losses and thefts were a potential signal of diversion and concluded that “drug diversion in hospitals is a serious and urgent concern that requires immediate attention to mitigate harms”.[31]

While unexplained losses within the supply chain may be perceived as low volume incidents involving small amounts of controlled medicines, a recent media report highlighted the “unexplained loss” of $4 million worth of controlled medicines from a pharmacy.[32] It went on to analyse the scale and nature of medicines included in the report over a six-year period within the particular market. The top eight products in terms of volume and subject to losses amounted to 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

[27] van Dijk, J. (2006). “Attitudes of victims and repeat victims toward the police: Results of the international crime victims survey.” *Crime Prevention Studies*, volume 12. Retrieved from https://popcenter.asu.edu/sites/g/files/litvpz3631/files/library/CrimePrevention/Volume_12/03-van_Dijk-2.pdf.

[28] https://tapaemea.org/.

[29] www.pharmoutsourcing.com/Featured-Articles/342562-Pharmaceutical-Supply-Chain-Security-Risk-Assessment-for-Shipping-Lanes/.

[30] Dugato, M., and Sidoti, C. (2023). “The Organised Theft of Medicines”.

[31] Fan, M., Tscheng, D., Hamilton, M., Hyland, B., Reding, R., and Trbovich, P. (2019). “Diversion of Controlled Drugs in Hospitals: A Scoping Review of Contributors and Safeguards”. *Journal of Hospital Medicine*. Vol 14, issue 7. Retrieved from https://shmpublications.onlinelibrary.wiley.com/doi/full/10.12788/jhm.3228.

[32] www.cbc.ca/news/canada/unexplained-losses-prescription-drugs-1.7247602.

medicines and subject to enhanced controls relating to manufacture, distribution, storage and prescribing. One of the remaining medicines, while not classified as a controlled medicine, is known for its unlawful use in the manufacture of methamphetamine. The article emphasized the potential for these losses to be leaked into the illegal market.

Challenges exist in understanding the true scale of thefts across the supply chain. As discussed by Dugato and Sidoti,[33] the absence of clear and robust reporting systems will result in an incomplete understanding of the scale of the problem, reducing the opportunities to identify preventative opportunities and ultimately diminishing the warning flags that the effective reporting of thefts may highlight to authorities.

Theft of medicines or incidents categorized as "unexplained losses" are likely to contribute significantly to the illegal pharmaceutical trade and non-medical use, as well as posing risks of the reintroduction of these products into the supply chain under conditions that do not meet the quality standards of good distribution practice (GDP).[34] While beyond the scope of this handbook, once reintroduced, these stolen medicines can pose serious public health risks and are classified as falsified medicines, according to the WHO definition of falsified products.[35] Falsified medicines may include those that have unlawfully exited the regulated supply chain, with their origins deliberately misrepresented through fraudulent means.

Falsification of business records

Licensed entities diverting controlled medicines out of the regulated supply chain into illegal markets face the hurdle of maintaining the records required to avoid detection by regulatory authorities.

A common method to obfuscate diversion is through falsified records. One such technique involves creating fraudulent export documents, essentially generating "ghost exports". This entails fabricating documentation for the movement of controlled medicines, often indicating export to another country and frequently outside the region. This approach exploits potential gaps or inconsistencies in oversight between the various agencies responsible for monitoring legitimate pharmaceutical exports.

Such fraudulent methods have been used to mask wholesale volumes of diverted products, which are never exported and therefore do not arrive at the documented destination. This then provides the opportunity to fully account for the "sale and export" of pharmaceuticals and facilitate the diversion of controlled medicines into the illegal market. For example, an individual pleaded guilty to a charge of forgery of an invoice in order to mislead an inspector into believing medicines had been sold to a company outside the European Economic Area.[36]

By highlighting this method, we can improve the focus on potential vulnerabilities in the oversight system.

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[33] Dugato, M., and Sidoti, C. (2023). "The Organised Theft of Medicines".

[34] World Health Organization. "Good storage and distribution practices for medical products". https://www.who.int/publications/m/item/trs-1025-annex-7.

[35] World Health Organization. "The WHO Member State Mechanism on Substandard and Falsified Medical Products". Update 2022. Retrieved from www.who.int/publications/i/item/WHO-MHP-RPQ-REG-2022.01.

[36] www.gov.uk/government/news/pharmacists-who-illegally-supplied-more-than-55-million-doses-of-controlled-drugs-sentenced.

Patient diversion

While potentially involving lower individual volumes of product, an equal public health concern is the diversion of controlled medicines that have been legitimately dispensed to the relevant patient that are then "diverted" to a person for whom the controlled medicines were not intended. In an article entitled "Primary prevention of prescription opioid diversion: a systematic review of medication disposal interventions" by Schafer et al, it was concluded that between 50 and 75 per cent of non-medical users of prescription opioids in the United States obtained their tablets through diversion from friends and relatives.[37]

A range of academic research, mainly conducted within North America, has identified the source of diversion from patients as a common method by which drug dealers and non-medical users of pharmaceutical opioids obtain their products. Reported in an article by Inciardi et al, entitled "The black box of prescription drug diversion",[38] it was concluded that major sources of pharmaceutical diversion included:

- Friends and relatives
- Pain patients
- The elderly

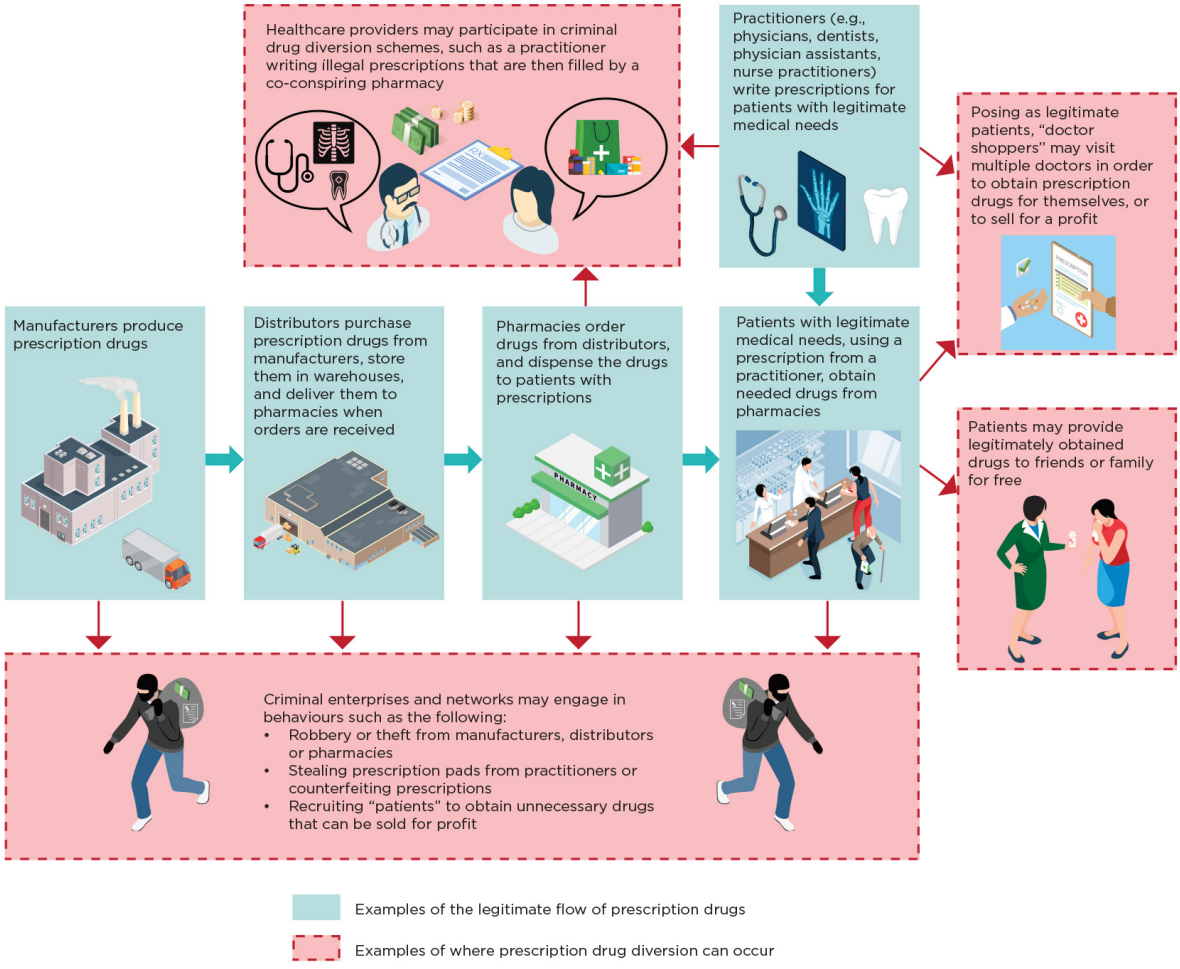
Subsequent research by Rigg et al in 2011[39] also identified the purchasing of pharmaceuticals from indigent patients to be a source of diversion.

[37] Schäfer, W. L. A., Johnson, J. K., Wafford, Q. E., Plummer, S. G., and Stulberg, J. J. (2021). "Primary prevention of prescription opioid diversion: a systematic review of medication disposal interventions". *The American Journal of Drug and Alcohol Abuse*.

[38] Inciardi, J. A., Surratt, H. L., Cicero, T. J., Kurtz, S. P., Martin, S. S., and Parrino, M. W. (2009). "The 'Black Box' of Prescription Drug Diversion". *Journal of Addictive Diseases*. vol 28, issue 4.

[39] Rigg, K. K., Kurtz, S. P., and Surratt, H. L. (2012). "Patterns of prescription medication diversion among drug dealers". *Drugs: Education, Prevention and Policy*. vol 19, issue 2.

Figure 2. An example of the prescription drug supply chain and opportunities for abuse and diversion



Source: https://www.gao.gov/assets/d15471.pdf (p. 9)

2.3 Impact of diversion

The examples of diversion methodologies described in this handbook include systematic, wholesale, organized illegal approaches conducted by organized crime groups and criminal enterprises. The objective of these criminal methodologies is to divert controlled medicines into the illegal market for criminal profit.

A key finding of the UNODC *World Drug Report 2023* (availability of pharmaceutical opioids) revealed that the availability of prescription opioids (controlled under the 1961 Single Convention and the 1971 Convention on Psychotropic Substances) for medical consumption continues to decrease as a result of reduced consumption in high-income countries. Despite this trend, such countries maintain high overall consumption rates. Meanwhile, the availability of prescription opioids for medical purposes in low- and middle-income countries remains low.[40]

[40] www.unodc.org/unodc/en/data-and-analysis/wdr-2023-online-segment.html.

The demand by individuals outside of medical supervision for non-medical use of controlled medicines is significant, as was graphically presented in the BBC television documentary series entitled "Drugs Map of Britain". The series included an episode entitled "Scotland's Valium Crisis" and highlighted how the illegal market supplies various forms of diazepam, including legitimately manufactured and diverted versions of diazepam supplied by criminal actors, along with unlicensed, substandard and falsified controlled medicines, catering to those individuals seeking such substances. While not all these products are illegally diverted from the regulated supply chain, one of the dangers of the non-medical use of products purchased from illegal sources is that they can contain highly dangerous undisclosed ingredients. Recent reports have highlighted cases of serious outcomes where individuals have purchased what they believe to be controlled medicines from illegal sources, which are later discovered to have been adulterated with ingredients such as nitazenes.[41]

To satisfy and respond to the supply demands of the non-medical use of controlled medicines by individuals requires a range of illegal methods to access the volume required. One of the significant methods utilized to meet this demand is the illegal diversion of regulated supply chain-controlled medicines. The detrimental impact of controlled medicine diversion activity has the potential to result in significant negative outcomes including:

- Reducing the availability of controlled medicines in the healthcare system for legitimate dispensing
- Patients failing to access the most appropriate medication to meet their identified clinical needs due to lack of availability within the regulated supply chain
- Patient harm or death due to receiving tampered products
- Increased public health risks to individuals sourcing and consuming illegally available controlled medicines for non-medical use outside of medical prescribing and supervision. Such risks involve the dangers of overdose, addiction and the use of controlled medicines with no understanding of their source or ingredients with the potential for tragic outcomes
- Significant cost to the healthcare system whereby controlled medicines are diverted out of the supply chain fraudulently at cost to the local public health system. A recent example reported in the Italian media highlighted a cost of 65,000 euros to the public health system from a single investigation where controlled medicines were obtained at zero cost utilizing fraudulent prescriptions
- Greater demand for ever increasing volumes of controlled medicines to meet wholesale and distribution needs in the supply chain from markets experiencing diversion
- Increased manufacturing capacity targeted to meeting the increased supply chain demand from existing markets experiencing diversion. This has the potential to absorb manufacturing capacity with the knock-on effect of reducing the manufacturers' ability to supply and provide access to controlled medicines to new and other existing markets
- Creation of a chilling effect whereby the fear of diversion of controlled medicines results in government authorities implementing additional criminal and regulatory controls to counter the threat. The unintended consequences of such controls undermine the

[41] RADAR alert issued on new synthetic drug xylazine - News - Public Health Scotland.

global priority of increasing fair and equitable access to controlled medicines thereby compounding or leading to the reduction of legitimate patient access

As highlighted in the WHO publication “Left behind in pain”, there is an identified global disparity in access to morphine and other opioids with the lack of availability in low-income countries being one of the outcomes of this disparity. The overall global effect of not responding proportionately and effectively to the diversion of regulated supply chain-controlled medicines will result in continuing inequity of access and availability of such medicines in low- and middle-income countries.

3. Countering diversion risks

The following sections of the handbook are designed to provide the reader with a menu of tactical and strategic options to counter the diversion of controlled medicines. These options are supported with examples of identified effective practice gathered from global authorities and utilized in their mission to counter the diversion of controlled medicines and ensure safe and secure regulatory supply chains.

The European Union Drugs Agency (EUDA) in its report "Heroin and other opioids – In depth analysis" highlights the need for increased vigilance by all partners to prevent and identify potential diversion from the legitimate supply chain for prescription opioids. This approach is reflective of other similar approaches in published technical products such as:

- The UNODC publication *Combating Falsified Medical Product-related Crime*
- "The WHO Member State Mechanism on Substandard and Falsified Medical Products"

One of the consistent priorities of these technical products is the maintenance of a safe and secure regulated supply chain to sustain supply chain integrity and protect patient health. The risk of diversion of controlled medicines can result in high quality, legitimately manufactured products being illegally removed from the supply chain and trafficked into the illegal market. The overlying strategic counter diversion imperative of this handbook is to maintain a safe and secure supply chain as a priority responsibility for all licensed entities and actors within the supply chain while ensuring the continued access to and availability of controlled medicines across all communities.

Effective legislation for the implementation of a regulated supply chain and the related obligation established by the conventions and applicable to all States Parties, constitute the backbone of any efforts to prevent diversion of controlled substances. Within the scope of this document, the key strategic building blocks for the development of an effective counter diversion strategy to ensure a safe and secure regulated supply chain will include:

- Data analysis and monitoring
- Regulatory standards, inspection and investigation
- Due diligence and third-party risk management
- Training and education
- Collaboration, coordination and communication

These building blocks have global applicability and, while requiring adaptation within local contexts, will form threads that run throughout this handbook and within the menu of tactical options described within each area of focus.

To provide a recognizable and consistent framework for international partners, the menu of tactical options to counter the threat of diversion of controlled medicine comprise three broad strategic themes:

- Prevention
- Detection
- Response

3.1 Prevention

Information on the scale of the diversion of controlled medicines is limited. As previously highlighted, most of the research into the problem focuses on opioid diversion issues in the United States and Canada aligned to the scale of per-capita users.[42] In the research conducted by Alho et al (2015), it was concluded that diversion and misuse of opioids is a significant global public health challenge with an estimated prevalence of diversion of between 23 and 39 per cent of cases. The review also concluded that greater understanding of the impact of misuse and diversion was required.[43] Furthermore, as reported in the research of Dugato and Sidoti, there is a growing trend in the reported cases of diversion of pharmaceuticals accounting for 72 per cent of pharmaceutical-related crime in 2020, as reported by the Pharmaceutical Security Institute.[44]

Data analysis and monitoring

A proactive approach to the ongoing monitoring of data generated from the supply chain can provide timely indicators of potential diversion activity and allow for earlier intervention. Additionally, supply chain data can assist in the monitoring of patient access and availability of controlled medicines within the market. A data collection plan should be developed to ensure a systematic approach, considering all forms of relevant information which will assist in understanding issues and risks within the regulated supply chain, i.e. facilitating the reporting of incidents. A key source of data will include the yearly reporting requirement to INCB.

In ensuring increased availability of and access to controlled medicines while being mindful of the risk of the diversion of controlled medicines, at a national level, it is important that authorities fully understand their local context and healthcare market. One method by which this can be achieved is through the utilization of all relevant data. This may include supply chain aggregated volumes of controlled medicine data assessed against the identified local demand, prescribing data and clinical and prescribing practice. This can provide a framework

[42] International Narcotics Control Board. (2016). Narcotic Drugs 2016. www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2016/Narcotic_Drugs_Publication_2016.pdf.

[43] Alho, H., D'Agnone, O., Krajci, P., McKeganey, N., Maremmani, I., Reimer, J., Roncero, C., Somaini L., Wright, N., and Littlewood, R. (2015). "The extent of misuse and diversion of medication for agonist opioid treatment: A review and expert opinions". *Heroin Addiction and Related Clinical Problems*. Vol 17.

[44] Dugato, M., and Sidoti, C. (2023). "The Organised Theft of Medicines".

in which to assess the volume and strengths of controlled medicines moving through the supply chain against identified patient requirements:

- Do the overall prescribing volumes of differing strengths of controlled medicines align with local clinical/prescribing guidance?
- While the overall volume of controlled medicines in the supply chain remains consistent, is an increased demand for higher strength products emerging?
- When any anomalies or changes in supply chain volumes or strengths of controlled medicines are identified, are the causes fully understood and the related risks assessed?

The non-medical use of controlled medicines by individuals can on occasions be facilitated with the additional non-medical use of other non-controlled medical products. An example of this is the non-medical use of a product with the street name of "Lean" or "Purple Drank".[45] This product is a recreational drug cocktail that consists of codeine linctus (an opiate) and promethazine (an antihistamine).[46] In many countries both codeine linctus and promethazine products are often available over the counter without prescription and therefore not subject to the same level of control as controlled medicines. This enables excessive purchasing[47] and, as a result, indicates other potential threats within the supply chain, such as the diversion of codeine linctus.

As a result, understanding the local/regional nature of the non-medical use of controlled medicines may provide opportunities to monitor additional indicators that offer early warning signals of threats to controlled medicines, such as:

- Are medicines (non-controlled medicines) used non-medically through the same mechanisms as controlled medicines?
- Are changes in the demand for these non-controlled products occurring?
- Are non-controlled medicines potentially vulnerable to such non-medical use subject to monitoring?

National medicine regulatory authorities working with licensed actors at all levels within the regulated supply chain should aim to actively collect, monitor and share appropriate information on production, sales and dispensing of controlled medicines. While aggregated national data may provide an overall picture of the volume of controlled medicines within the regulated supply chain, other potential signs of diversion may not be recognized or apparent within national level volumes. For example, a single rogue actor within the supply chain may be obscured simply through the sheer volume of supply chain movement. Such an approach underpins the principles of maintaining supply chain integrity, safety and security. Data analysis increases the ability to identify changes in supply patterns and the emergence of abnormal activity or suspicious profiles that may indicate possible illegal activity.

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[45] Chiappini, S., Schifano, F., Corkery, J.M., and Guirguis, A. (2021). "Beyond the 'purple drank': Study of promethazine abuse according to the European Medicines Agency adverse drug reaction reports". *Journal of Psychopharmacology*, 2021, Vol. 35(6) 681 –692.

[46] https://nationalrehabhotline.org/rehab-questions/what-is-lean/.

[47] Chiappini et al (2021). "Beyond the 'purple drank'."

Data analysis will allow for a more informed understanding of:

- Business-as-usual purchasing patterns of high-risk products
- Changes in purchasing patterns in terms of frequency, volume and strength profiles
- Patterns and volumes issued by prescribers, the profiles of products and strengths prescribed
- Changes in the level of individual pharmacy dispensing, volume and strength of products
- Reported levels of thefts and losses from within the supply chain
- Nature of products reported stolen or lost, i.e. only high-strength controlled medicines, identification of patterns of such events and areas of supply chain vulnerability
- Lack of patient availability and access to controlled medicines

A proportionate approach by all actors within the supply chain also requires continued assessment of the availability and access to controlled medicines to ensure that sufficient volumes are available to meet local medical needs.

Where such strategies have not been effectively implemented, it has on occasions led to the instigation of legal or regulatory proceedings against entities who:

- Operate suspicious ordering monitoring systems
- Failed to investigate or report suspicious orders of controlled medicines

By failing to implement such strategies, these entities hinder the reporting of valuable intelligence on regulated supply chain purchasers of unusually high volumes of controlled medicines, many of whom may be involved in diversion. A recent case in the United States involving a pharmaceutical distributor failing to report unusually large orders of controlled medicines resulted in a $19 million settlement.[48]

In conclusion, a detailed understanding of the normal volumes and rhythms of the supply chain at every level assist in the identification of the abnormal activity while ensuring appropriate medical availability to patients.

Good distribution practices

The supply of controlled medicines is a highly regulated and licensed process. It is necessary therefore for individuals and entities involved in supplying these products to ensure compliance with the following:

- National legislation
- Local licensing requirements
- Good storage and distribution practice (GSDP)
- Good pharmacy practice
- Import and export licence requirements
- Associated legislation

[48] www.dea.gov/press-releases/2024/02/07/dea-announces-settlement-morris-dickson-co-llc.

They must ensure that they only supply controlled medicines to individuals or businesses that are licensed and otherwise authorized to receive them.

WHO has produced a technical report on good storage and practices for medical products that provides detailed insight into the key elements of this important area and the themes that contribute to an overall framework from which a local context-specific approach to GSDP can be developed.[49]

In line with the objectives of this guidance, it is further recommended that GSDP regulatory inspection activities by authorities recognize the potential threat of diversion and enhance their inspection programme regarding controlled medicines with activities such as:

- Targeted regulatory inspection activity to examine diversion-related issues
- Examining, as part of the inspection process, that all wholesalers supplying controlled medicines are subject to checks to confirm the presence of a current valid controlled drugs licence
- Ensuring wholesale dealers are following local guidance for the safe custody of controlled drugs and drug precursors in transit
- Checking the processes in place for wholesalers and distributors to identify suspicious or abnormal orders by customers

Due diligence and third-party risk management

To further reinforce GSDP procedures, appropriately detailed and embedded processes should be developed and utilized by all persons and entities supplying controlled medicines to ensure the legitimacy of all third parties[50] and an understanding of third parties' business-as-usual practices. The ability to achieve this can be divided into two aspects:

- Due diligence whereby documented checks in line with local regulatory requirements are conducted, e.g. existence of current licences.
- Third-party risk management (TPRM) whereby all businesses supplying products to customers will want to ensure a detailed understanding of their third parties. In most supply chain-related businesses, this aims to ensure the supplier is best able to meet the needs of their customer. Within the context of controlled medicines, such understanding is symbiotic, given that it also assists the supplier in developing an understanding of each customer's normal consumption patterns and, as a result, a potential to identify possible abnormal activity.

The importance of the wholesalers distribution authorization (WDA) within this process cannot be overstated. For an entity to sell or supply medicines to anyone other than the patient using the medicine, possession of a wholesale distribution authorization, also known as a wholesale distribution licence, is mandatory. WDAs are issued by the national medicines regulatory authority with responsibility for the relevant jurisdiction.

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[49] World Health Organization. (2020). "Good storage and distribution practices for medical products".

[50] The concept of "third party" (or counterparty) includes any individual or legal entity external to a company or institution with which the company or institution has, or might have, a commercial or collaborative relationship. It includes, for example, suppliers, subsuppliers, partners, dealers and customers (Crime&tech, 2024).

To maintain a WDA the entity must also:

- Comply with GSDP standards, and pass regular inspections
- Have a suitably experienced "responsible person" named on the licence to ensure that medicines are procured, stored and distributed appropriately

The WDA issued will display key information that, once the authorization has been checked for authenticity, must also be cross-checked with:

- The proposed purchasing entity – is the purchaser the same as the entity authorized?
- Does the delivery location correlate with the address authorized?
- Does the proposed purchase comply with any conditions or restrictions at the point of issuance?

Any differences identified should immediately raise concern and be the subject of suitable enquiries.

The development of this approach can be supported by:

- A risk-based customer matrix prioritizing checks based on the volume, strength and nature of the products purchased
- Locally developed templates that ensure a consistent approach to information gathering, checking and documentation
- Agreed timescales for review

This can be further enhanced by:

- Training regulatory licensing professionals in the verification of identity documents, for example, passports and driving licences. This could also be expanded to include all regulatory GDP inspectors as part of the checks of key personnel during regulatory site inspections
- At all points of purchase, conducting a review of all relevant licences, for example, wholesale distribution authorization or be in possession of a controlled drug licence before the authorization of any sale
- Conducting a physical review of the legitimacy of relevant licences, for example, to combat the utilization of "scam" copied online licences by bad actors
- A requirement throughout the entirety of the supply chain, from the point of manufacturing to the dispensing of prescriptions, for all entities to have clearly defined "know-your-customer" processes
- Ensuring heightened due diligence checks for high-risk purchases (exports), for example, relevant licences (WDA, controlled drugs, and export and import authorizations) of all parties involved in the purchase and supply

Although the WDA certificate is a crucial requisite, an effective TPRM process cannot be confined to this alone. Pharmaceutical institutions and companies do not operate in isolation but are embedded within a complex supply chain comprising networks of external entities, such as companies, professionals or brokers, that criminals might exploit to steal, divert or

launder pharmaceutical products.[51] This complexity calls for a robust understanding of all counterparts, which necessitates a systematic, comprehensive, formalized and regularly updated mapping of processes and relationships where significant risks might exist.

Effective TPRM entails several mandatory features and goes beyond "list-based" checks, such as white lists (e.g., WDA or GDP authorizations) or blacklists (e.g., sanctioned entities, politically exposed persons, adverse media or enforcement actions). These approaches, while relevant, can be insufficient for several reasons. First, list-based checks can only detect past and confirmed risks or known problematic situations but fail to identify potential future risks. Moreover, evolving criminal behaviours increasingly involve less visible forms of supply chain infiltration (e.g., fraudulent, fiscal or financial crimes), making them less likely to attract attention in local or international media.

A mature TPRM framework can leverage advanced risk analysis and anomaly detection related to third parties. This approach should encompass various dimensions of corporate operations, such as ownership structures, financial and accounting setups, territorial exposures (both local and international) and a company's lifecycle. By adopting such methodologies, organizations can identify risks not yet flagged by regulatory authorities or open sources.[52]

For instance, under the European-funded MEDI-THEFT project, researchers from Università Cattolica del Sacro Cuore-Transcrime[53] and its spin-off Crime&tech[54] developed and tested a set of risk indicators designed to identify suspicious anomalies within companies. These indicators are rooted in research on the infiltration techniques of criminal organizations in the legal economy. An exploratory analysis within the MEDI-THEFT project, covering over 57,000 active European companies in the pharmaceutical and logistics sectors, revealed that approximately 3 per cent exhibited a very high risk of being shell companies.[55]

A shell company is a company without active business operations or significant assets. These types of companies are not all necessarily illegal, but they are sometimes used illegitimately, such as to disguise business ownership from law enforcement, business or the public.

This highlights the critical need for proactive and data-driven TPRM processes that can adapt to evolving risks and support compliance with emerging regulatory and security demands.

Disposal processes for unused, returned and expired controlled medicines

The disposal of unused or no longer required controlled medicines is a fundamental primary prevention strategy that can contribute to combating diversion.[56]

Strategies that recognize this issue and provide practical methods for removing unused controlled medicines from circulation have been reported as being highly effective in contributing to a reduction in the availability of prescribed controlled medicines that may

[51] Dugato, M., and Sidoti, C. (2023). "The Organised Theft of Medicines".

[52] https://crimetech.it/wp-content/uploads/2024/06/Report_La-valutazione-e-gestione-del-rischio-terze-parti-in-Italia.pdf. (in Italian).

[53] www.transcrime.it.

[54] www.crimetech.it.

[55] www.safe-europe.eu/project/medi-theft/video/index.html.

[56] Schäfer et al, "Primary prevention of prescription opioid diversion".

become at risk of diversion. At a global level, WHO has produced interagency guidance for national authorities on the safe disposal of unwanted pharmaceuticals.[57]

In many countries procedures exist which are publicly available that provide an opportunity for individuals to safely dispose of unwanted medicines. An example of such an approach has been implemented by the Australian Therapeutic Goods Administration (TGA) – Safe disposal of unwanted medicines.[58] Available on the TGA website, this information describes the process as follows:

> Your local community pharmacy provides a free and convenient way to dispose of your unwanted medicines responsibly. Prescription medicines, over-the-counter medicines, herbal or complementary supplements, gels, liquids, creams and pet medicines can all be returned to your community pharmacy for free, safe disposal.

TGA has additional supplementary guidance for individuals to specifically deal with unused prescription opioids.[59]

In addition to embedded processes that assist individuals to safely dispose of unwanted medicines, some jurisdictions run campaigns specifically focused on removing unwanted medicines from circulation. In the United States, an ongoing government initiative named "National Prescription Drug Take Back Day" is one approach for dealing with this issue. Reported returns for the month of April 2024 stated that 335 tons of medicines were "taken back".[60] Local reporting of the volume of dispensed medicines collected as part of the United States strategy over multiple years highlights the vast number of doses that, as described in the 2015 research of Schafer et al, could have become the subject of diversion.

The secure removal and destruction of unused or expired medicines from manufacturers, wholesalers and pharmacies is equally relevant. Such processes should include authorizations and the monitoring of destruction by appointed persons.[61] Strategies should also include clear accountability over disposal storage facilities and the auditing of disposal contractors to ensure that controlled medicines intended for final destruction are not diverted back into the regulated supply chain or enter illegal market supply routes.

Training, education and engagement

The prevention of diversion of controlled medicines requires a coordinated multidisciplinary approach through engaged partnerships involving relevant stakeholders. All stakeholders possess skills, knowledge and insight regarding local contexts which can contribute to understanding the risks of diversion and therefore lead to the development and implementation of appropriate preventative approaches.

In pursuing a partnership approach, regular engagement with stakeholders will build confidence and improve the flow and effectiveness of communication across the span of

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[57] World Health Organization. (1999). "Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies". www.who.int/publications/i/item/guidelines-for-safe-disposal-of-unwanted-pharmaceuticals-in-and-after-emergencies.

[58] www.tga.gov.au/safe-disposal-unwanted-medicines.

[59] www.tga.gov.au/resources/publication/publications/return-your-unused-opioids-resource-kit.

[60] www.dea.gov/takebackday.

[61] www.england.nhs.uk/south/wp-content/uploads/sites/6/2019/06/8-guidance-on-destruction-cds.pdf.

professionals within the healthcare sector. This may include the sharing of relevant and emerging threats of diversion posed by bad actors or particular controlled medicines that may be at increased risk. Relevant preventative steps and effective communication can develop greater awareness of reporting processes for:

- Wholesalers
- Community pharmacies (retail pharmacies)
- Medicine regulators (national regulatory authorities)
- Healthcare professionals
- Other regulatory agencies, for example, pharmaceutical regulators

Additionally, effective communication can inform the completion of a local threat assessment and the development of locally relevant counter diversion plans. As part of a broader local engagement strategy, joint multidisciplinary training and information-sharing events can be developed. The objectives of such events may include:

- Increasing knowledge and awareness of each partner's role and powers
- Increasing knowledge and understanding of diversion and signals that may indicate emerging problems
- Awareness-raising of local response plans when diversion incidents are identified
- Mentorship to young healthcare professionals
- Ongoing continued professional development for existing healthcare professionals
- Tabletop exercises to stress test local procedures
- Increasing trust and confidence in working with partners
- Identifying collaborative opportunities
- Identifying intelligence development opportunities

An example of effective engagement and knowledge-sharing is provided by the United States Drug Enforcement Administration who have produced an informative pharmacist's guide to prescription fraud.[62] This compact guide reinforces the important role that pharmacists play in the first line of defence in preventing and detecting prescription fraud. The guide provides helpful hints and tips while highlighting the objective of ensuring that controlled medicines "continue to be available for legitimate medical and scientific purposes, while preventing their diversion into the illicit market".

Along with supply chain actors, the initial training and subsequent ongoing professional development of healthcare professionals across the diversity of such roles should aim to equip them with the knowledge and awareness to identify potential diversion signals and thus prevent diversion. This supports a multidisciplinary approach to the risks of diversion. The areas of training and knowledge-sharing need to recognize local contexts and be relevant to a multidisciplinary audience in order to maximize benefits.

[62] www.deadiversion.usdoj.gov/GDP/(DEA-DC-002R1)(EO-DEA009R1)_RPH_Guide_to_RX_Fraud_Trifold_(Final).pdf.

PREVENTION SUMMARY

Proactive data analysis and monitoring

Regular review of trends to support appropriate use and identify emerging concerns:

- Do the overall prescribing volumes of differing strengths of controlled medicines align with local clinical/prescribing guidance?
- While the overall volume of controlled medicines in the supply chain remains consistent, is an increased demand for higher strength products emerging?
- When any anomalies or changes in supply chain volumes or strengths of controlled medicines are identified, are the causes fully understood?
- Does the volume of controlled medicines within the regulated supply chain meet with identified clinical need?

Good distribution practice

Oversight of wholesale practices to support safe distribution and identify abnormalities:

- Targeted regulatory inspection activity to examine diversion-related issues
- All wholesalers supplying controlled medicines are subject of checks to confirm the presence of a current valid controlled drugs licence
- Ensuring wholesale distributors are following local guidance for the safe custody of controlled drugs and drug precursors in transit
- Checking that processes are in place for wholesalers and distributors to identify and, where appropriate, report suspicious or abnormal orders by customers

Due diligence and third-party risk management

Strengthening governance to reduce third-party risks:

- Ensure all licensed entities comply with the good storage and distribution practice (GSDP) standards, and pass regular inspections
- Ensure all licensed entities have a suitably active and experienced “responsible person” named on the licence
- Verification processes in place to confirm the legitimacy of customers by checking their licences, operations and purchasing patterns
- Develop/implement robust systems to flag suspicious orders

Secure disposal of controlled medicines

Establishing safe disposal practices to further minimize risks:

- Develop/implement and publicize mechanisms for the safe disposal of unused or expired medicines to prevent diversion or misuse

Training and collaboration

Building stakeholder capacity and coordination to support safe access and mitigate diversion risks:

- Train stakeholders (regulatory staff, wholesalers, healthcare providers) in need of access, appropriate use of controlled medicines and recognition of risks of diversion
- Development of multidisciplinary collaboration across the supply chain to improve awareness of risk and sharing of preventative strategies

3.2 Detection

The detection of incidents that may indicate the ongoing diversion of controlled medicines requires a broad collaborative partnership approach. Signals that diversion is ongoing may initially be identified by a range of agencies or authorities nationally and internationally due to the transnational nature of diversion. Given the often specialized nature of pharmaceutical crime, some authorities may not immediately recognize the significance of the information they possess or specific findings from the field.

Strategic approaches to the differing challenges of pharmaceutical-related crime, for example, the Council of Europe's Medicrime Convention[63] and the WHO Member State Mechanism on Substandard and Falsified Medical Products,[64] recognize the importance of collaboration and communication by stakeholders for a coordinated response.

Indicators that diversion may be occurring include:

- Physical indicators involving the seizure of controlled medicines in the illegal market such as:
  - Detection of small parcels in the postal system containing controlled medicines
  - Seizures of such medicines by customs authorities
  - Discovery of controlled medicines in unauthorized locations
  - Recovery of controlled medicines in cases involving other criminality
- Virtual indicators:
  - Online sales of controlled medicines through unlicensed or unapproved sources
  - Advertisements offering controlled medicines on platforms known for illegal activity
  - Social media posts about the use and supply of controlled medicines

A structured approach to sharing information, developing relevant intelligence and agreeing appropriate responses is key to ensuring a coordinated response, both in a proactive and reactive manner. Progress can be made by observing the points listed below.

Collaboration and education of law enforcement authorities

A coordinated approach with local authorities can ensure greater reach by working with those most likely to provide additional resources. This can utilize financially neutral business-as-usual activities to detect indicators of diversion or through an agreed coordination process allowing tasking to proactively identify possible indicators of diversion. This approach could be further enhanced by ongoing joint training to raise awareness of all participants and an understanding of the roles, powers and abilities of partners. Within the local context, authorities may include:

- Medicine regulators
- Police forces
- Customs agencies

[63] https://rm.coe.int/medicrime-10-questions-and-answers-eng/168096d6bc.

[64] World Health Organization. (2022). "The WHO Member State Mechanism on Substandard and Falsified Medical Products", update 2022. www.who.int/publications/i/item/WHO-MHP-RPQ-REG-2022.01.

- Criminal justice authorities
- Other regulatory authorities, such as pharmacy regulators
- Other national enforcement agencies, such as trading standards

Collaborative approaches enhance the engagement of all stakeholders, leading to a more detailed understanding of ongoing diversion, allowing mutually beneficial joint partnership opportunities to be maximized. Moreover, partnership working can be facilitated by the joint development of an information exchange tool to aid the lawful and systematic exchange of information, signed by all parties to meet local legal requirements.

Key elements of local collaborative working typically involve:

- Operational tasking and coordination meeting processes allowing agreement o responses to identified threats
- Regular joint agency meetings to enhance strategic relationships
- Agreed information exchange processes
- Operational contact network
- An ongoing programme of joint training and education for operational staff

Joint targeted monitoring by stakeholders

The effectiveness of partnerships can be enhanced by the development of specific methods and plans based on local intelligence and tailored to meet the needs of the local context. Examples of these efforts include the development of tools or processes specifically focused upon the threats of diversion, for example:

- The regulator, working with local partners, to develop a watch-list of controlled medicines assessed within the local context to be most vulnerable to diversion from the regulated supply chain. This list is to be disseminated to licensed entities in the supply chain and other enforcement authorities to use in the market and be subject to monitoring and review through partnership engagement.
- Manufacturers and wholesale distributors to proactively monitor transactions, investigate any irregularity in the sales patterns of controlled medicines and share information where appropriate.
- Proactive monitoring of sales patterns to identify concerns that may indicate suspicious behaviour or constitute diversion or misuse of medicinal products. This will allow early assessment and, if appropriate, the reporting to competent authorities where necessary, based upon agreed indicators, e.g. frequency of purchases, volume or strength profiles of high-risk products.
- Reporting to authorities, by parties within the licensed supply chain, issues of suspicious activity or concern.

The joint technical report by the International Pharmaceutical Federation (FIP) and WHO entitled “Guidelines on good pharmacy practice: standards for quality of pharmacy services

(GPP)"[65] also provides some relevant direction for the challenges of illegal diversion. GPP specifies a mission of pharmacy practice which comprises six components that include:

- Preventing harm from medicines
- Making responsible use of limited health-care resources

GPP further suggest that:

- A system should exist that enables pharmacists to report medicine-related problems, misuse or detection of counterfeit products.

The identification and reporting by pharmacists to authorities of significant changes relating to the prescribing of controlled medicines is another tool in a wider healthcare response to potential concerns of diversion and non-medical use.

Following the 2016 report of the Advisory Council on the Misuse of Drugs (ACMD), commissioned by the Government of the United Kingdom, on the diversion and illicit supply of medicines,[66] the subsequent Government response listed eight specific recommendations. The first recommended the maintenance of "a watch list of emerging prescribed substances with the potential for diversion and illicit supply."[67] Along with other recommendations, this one was the result of the extensive research undertaken by ACMD following the discovery of significant diversion of controlled medicines from the regulated supply chain.

Communication and threat awareness

Knowledge of the scale of diversion is limited by the complexity of illegal activity. However, it is also influenced by the range of differing agencies that interact with different elements of the supply chain and areas of potential wrongdoing. Simplification and promotion of reporting mechanisms will assist in the increase and timely reporting of incidents and concerns. Ways in which this might be achieved could include:

- Implementation of single point of reporting mechanisms relevant to all actors in the supply chain
- Creation of whistleblowing mechanisms, with the possibility of anonymous reporting, to remove potential barriers to reporting suspected wrongdoing or concerns
- Development of a counter diversion communication strategy targeting audiences across manufacturing, wholesaling and healthcare professionals, along with the wider public – if you suspect it, report it
- Increasing the risk awareness of all customers within the regulated supply chain[68]
- Through the creation of standing working groups, develop regular liaison between regulatory bodies, enforcement agencies, for example, police, customs, private business and healthcare professionals to establish and highlight current diversion

[65] www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs961-annex8-fipwhoguidelinesgoodpharmacypractice.pdf.

[66] https://assets.publishing.service.gov.uk/media/5a81733ced915d74e33fe464/Meds_report-_final_report_15_December_LU__2_.pdf.

[67] https://assets.publishing.service.gov.uk/media/5a82df2f40f0b6230269d24e/2017_ACMD_response_illicit_medicines.pdf.

[68] www.transcrime.it/wp-content/uploads/2024/06/Project-CAPSULE_Report.pdf.

threats and risks. This approach will enhance joint coordinated responses by authorities and, where appropriate, timely sharing with wholesalers, manufacturers and other supply chain actors

To further enhance communication, strategic messaging to actors in the supply chain, raising threat awareness, would reinforce prevention and detection opportunities. An appropriate strategy may include messaging on good distribution practice and highlighting reported or current fraudulent methodology or indicators.

Examples of targeted strategic messaging might include awareness-raising to support manufacturers, distributors and wholesalers, highlighting suspicious signals and methodologies that have emerged in their local market which may be indicative of diversion activity, such as requests by customers to:

- Redirect deliveries to previously unknown alternative premises
- Exchange deliveries in a public space from delivery van to alternative van
- Deliver to an address not specified on the wholesale distribution authorization (WDA)

Communications could additionally utilize such messaging to promote reporting mechanisms and local regulatory requirements if concerns or suspicions are identified by a licensed entity.

Examples of supply chain vulnerability and risk are described in annexes 1 and 2.

Online monitoring, assessment and awareness of supply chain product availability within illegal online marketplaces

The illegal online sale of medicines is a significant challenge for authorities[69] and likely to impact countries to varying degrees. As a result, it is prudent to consider the implementation of an online strategy to monitor, assess and detect illegal online sales. Such a strategy, due to the many elements required to facilitate the illegal online sale and supply of pharmaceuticals, will necessarily benefit from a broad partnership approach and include:

- Collaboration with enforcement agencies includes working with customs agencies at points of entry and borders where goods are subject to checks and seizures, as well as with police and other investigative agencies with an online presence
- Engagement with the private sector, such as logistic and fast parcel service providers whose services may be exploited to traffic diverted controlled medicines by those illegally selling to “customers”
- Joint working with online service providers, such as. social media platforms, where controlled medicines may be illegally advertised and sold

[69] www.interpol.int/News-and-Events/News/2023/Global-illicit-medicines-targeted-by-INTERPOL-operation.

- A monitoring programme to aid the identification of illegal advertising of controlled medicines
- An ability to test purchase advertised controlled medicines (the purchasing of products online covertly using a pseudonym) from identified illegal online sources to ascertain the nature of the product being offered, for example, diverted regulated supply chain-controlled medicines and falsified controlled medicine, thereby allowing the development of an informed local response
- Engagement with international and regional initiatives

The INCB paper "Guidelines for Governments on Preventing the Illegal Sale of Internationally Controlled Substances through the Internet"[70] provides a high-level perspective on areas of potential focus and development for authorities. The guidelines have been developed to assist in the production of national legislation and policies for "prescribers, pharmacists, law enforcement authorities, regulatory authorities and the public regarding the use of the Internet to dispense, purchase, export and import internationally controlled substances". Areas of focus include cooperation and collaboration and investigative standards as well as training reflecting global learning and experience.

The threats posed by illegal online pharmaceutical sales are at different stages of maturity across the globe and are not purely limited to supply chain medicines. However, there seems to be a clear requirement for all authorities to understand their local context and implement a proportionate strategy focused on prevention, detection and response through increased Internet vigilance.

[70] www.incb.org/documents/Narcotic-Drugs/Guidelines/internet/NAR_guide_Internet_guidelines_English.pdf.

DETECTION SUMMARY

Assessment of indicators that diversion may be occurring

Physical indicators involving the seizure of controlled medicines:

- Detection of small parcels in the postal system containing controlled medicines
- Seizures of such medicines by customs authorities
- Discovery of controlled medicines in unauthorized locations
- Recovery of controlled medicines in cases involving other criminality

Virtual indicators:

- Online sales of controlled medicines through unlicensed or unapproved sources
- Advertisements offering controlled medicines on platforms known for illegal activity
- Social media posts about the use and supply of controlled medicines

Collaboration and education of law enforcement authorities

Key elements of local collaborative working typically involve:

- Operational tasking and coordination meeting processes allowing agreement on responses to identified threats
- Regular joint agency meetings to enhance strategic relationships
- Agreed information exchange processes
- Operational contact network
- An ongoing programme of joint training and education for operational staff

Joint targeted monitoring by stakeholders

Collaborative tracking by regulators and supply chain actors:

- The regulator, working with local partners, to develop a watch-list of controlled medicines vulnerable to diversion
- Manufacturers and wholesale distributors to proactively monitor transactions, investigate irregularity in sales patterns of controlled medicines and sharing information where appropriate

Communication and threat awareness

Clear reporting channels and outreach campaigns to identify and address diversion risks:

- Implementation of single point of reporting mechanisms
- Creation of whistleblowing reporting mechanisms
- Development of a counter diversion communication strategy targeting audiences across manufacturing, wholesaling and healthcare professionals, along with the wider public – if you suspect it, report it

Online monitoring, assessment and awareness of supply chain product availability within illegal online marketplaces

Coordinated efforts with public and private stakeholders to detect illegal online sales of controlled medicines:

- Collaboration with enforcement agencies:
  - Customs agencies at points of entry and borders
  - Police and other investigative agencies with an online presence
- Engagement with the private sector, such as logistic and fast parcel service providers
- Joint working with online service providers, such as social media platforms
- A monitoring programme to identify illegal advertising of controlled medicines
- Development of a "test purchase" capability to allow assessment of products
- Engagement with international and regional initiatives

3.3 Response

Upon the identification of incidents involving suspected diversion of controlled medicines, it is critical to assess the scale of risk and take actions in a timely manner. With risks to both the ongoing safety and security of the supply chain and wider public health, an effective and coordinated response is key. The immediate priorities will include:

- Assessing the impact upon public safety
- Resecuring of the supply chain to prevent further reoccurrence of diversion

Advance planning

Planning the response to incidents through the engaged involvement of relevant local authorities will aid the production of an immediate effective response, which can be underpinned by the agreement of coordinated documented protocols or standard operating procedures. Such protocols should unambiguously articulate how the local response to the diversion of controlled medicines will be managed, providing clarity for all relevant parties.

An issue which has repeatedly emerged following the identification of the diversion of controlled medicines is the establishment of investigative primacy in relation to a medicine which has dual status, i.e. it is controlled both as a medicine and as a controlled drug by differing government authorities. Learning from previous cases, following the reporting of diversion of controlled medicines, has highlighted protracted discussions between police authorities and national medicines regulatory agencies on who has investigative primacy while the diversion problem continues unabated.

A key part of advance planning is to ensure clarity on which government authority will have investigative primacy in relation to medicines that are the subject of dual controls, i.e. controlled medicines, to ensure an effective and timely response, should an investigation be required. To embed local decision-making, a clear position should be agreed on among all relevant parties and documented as part of the standard operating procedures of the affected authorities.

In addition, the following strategic issues may also be considered as part of the development planning between relevant authorities and other supply chain actors and contribute towards an effective response phase to diversion incidents:

- Single points of contact in place with key authorities to ensure immediate and effective communication
- Local partnership network to facilitate rapid information sharing and cooperation with relevant stakeholders
- Implementation of information and intelligence exchange processes that meet local legal requirements
- The facility to hold a multi-agency response group to coordinate relevant stakeholders to:
  - Maximize differing skills, experience and powers of those invited to participate
  - Ensure clarity of roles and responsibilities
  - Safeguard a cohesive investigative approach
  - Complete a holistic risk assessment of the circumstances of the diversion risks
  - Develop an agreed risk mitigation plan
  - Ensure a coordinated response to media concerns
- In recognition of the transnational nature of the diversion of controlled medicines, to develop and, where appropriate, participate in regional and international liaison networks and initiatives to facilitate the sharing of information and response to identified incidents
- Clear processes to assess the legitimacy and source of any suspected diverted controlled medicines that have been seized by authorities

Criminal investigations

Criminal allegations referred to or identified by authorities can involve licensed individuals within the regulated supply chain or are perpetrated by actors outside the licensed environment. Whatever the circumstances it is critical that all referrals which result in a criminal investigation are conducted proportionately, diligently, thoroughly and fairly. Investigators should be trained to a high standard, qualified and experienced in the relevant jurisdiction's law and procedure. Investigators will also ensure, wherever possible and subject to legal constraint, that those referring cases, witnesses and the victims of breaches of medicines and associated legislation will be regularly updated on the progress of investigations.

The diversion of controlled medicines may be considered a complex environment for investigators and prosecutors, however, it is likely that commonly used criminal offences, such as theft, fraud and drug trafficking, will form the basis of any criminal diversion investigation. The UNODC resource *Combating Falsified Medical Product-related Crime: A guide to good legislative practices* provides helpful guidance which is also highly relevant to the investigative response to the diversion of controlled medicines. In line with other pharmaceutical crime investigative response, it is crucial that those charged with investigating diversion allegations do so within a framework that enables them to do so effectively.

As highlighted throughout this guidance, authorities responding to the diversion of controlled medicines may include law enforcement bodies, national medicines regulatory authorities responsible for the regulation of medical products, and, where local arrangements allow, multi-agency task forces comprising of experts from a range of relevant agencies. As covered in the UNODC *Combating Falsified Medical Product-related Crime: A guide to good legislative practices*, each jurisdictional framework and related investigative powers will necessarily differ, but may include the authority and ability to do the following, either through judicially approved orders or through police powers granted in that jurisdiction, when reasonable suspicion can be established:

Enforcement powers

Depending on jurisdiction, authorized bodies may exercise the following investigative and enforcement powers in response to diversion incidents:

- Stop, arrest and search persons, vehicles, vessels or other conveyances
- Enter and search premises, including vehicles
- Seize any weapon, device or means suspected of being involved in the commission of medical product-related offences
- Seize items used in the commission of medical product-related offences
- Freeze and seize proceeds of crime
- Initiate the recall and/or disposal of diverted medical products

Rapid response and scene management tools

To support immediate action following suspected diversion incidents, authorities may rely on the following tools for effective on-site response and evidence collection:

- Take photographs or make audiovisual recordings of a thing or place suspected of being involved in the commission of medical product-related offences
- Manage crime scenes
- Seize and analyse phones, computers and similar devices found in the possession of suspected offenders
- Request forensic information from specialized laboratories

Investigative efforts

Investigative efforts include a range of authorized actions to gather evidence and support legal proceedings:

- Question and interview witnesses, suspected offenders and other persons of interest, ensuring that all legal protections are employed
- Require the inspection or production of documents
- Obtain orders to access bank and financial records
- Unless consent is obtained, obtain orders to access telecommunications records
- Depending on the seriousness and scale of the alleged diversion, consider the use of special investigative techniques, such as wiretapping, controlled delivery and undercover investigations
- Consider obtaining authority to conduct test purchases to obtain samples by trained officers

Regulatory and administrative measures

Restricting access to authorizations and permits to prevent further misuse by suspected offenders:

- Suspend, modify and revoke authorizations, permits or certificates held by suspected offenders
- Disqualify suspected offenders from holding authorizations, permits or certificates

International and interagency cooperation

Collaborate to share information and coordinate investigations:

- Exchange information with foreign law enforcement agencies
- Coordinate joint investigations

Financial gain is the clear common motivation for organized crime groups and criminal enterprises to engage in the diversion of controlled medicines. As part of a holistic investigative strategy, it is important that the investigator considers how they will also tackle proceeds of crime generated through the crimes they are investigating. This may be achieved through the utilization of all available local legislation, i.e. joint working procedures with accredited criminal financial investigators. Such an approach can facilitate parallel financial investigations that progress and are coordinated alongside criminal investigations into breaches of medicines legislation. Proceeds of crime investigations may include money-laundering and the pursuance of confiscation proceedings where the evidence suggests that financial gain has been accrued by individuals involved in crime with medical products. Where local legislation allows, action taken may include the restraint and subsequent realization of assets. Confiscation hearings brought before the courts can result in the forfeiture of assets gained through criminal activity.

Cases reported in the media involving the diversion of controlled medicines provide examples of the effective use of proceeds of crime legislation. Subsequent enforcement action by authorities have highlighted seizures of high value property obtained through the proceeds of criminal activity involving medicines.[71]

The *United Nations Toolkit on Synthetic Drugs*[72] provides a range of resources including the topic of cybercrime. The information it contains includes a section on "Laundering the proceeds of trafficked synthetic drugs".[73] The resources available are highly relevant to the diversion of controlled medicines and subsequent money-laundering investigations. UNODC estimates that global money-laundering accounts for approximately 2.7 per cent of global gross domestic product.[74]

The effective use of financial investigation and the seizure of assets related to criminal activity can also be further utilized within an investigative communication strategy (see below)

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[71] https://cbsp.policja.pl/cbs/aktualnosci/215101,Leki-zawierajace-substancje-psychotropowe-wysylano-min-do-USA-rozbity-gang.html (in Polish).

[72] https://syntheticdrugs.unodc.org/syntheticdrugs/en/toolkit-index.html.

[73] https://syntheticdrugs.unodc.org/syntheticdrugs/en/cybercrime/launderingproceeds/index.html.

[74] Ibid.

highlighting the effectiveness of the criminal justice system and supporting the enhancement of community confidence in local authorities.

All investigators should be alive to other investigative possibilities to further their cases which support the overall investigative strategy. Where local legislation allows, this may include:

- Covert test purchasing of suspected diverted controlled medicines from illegal sources
- Directed covert surveillance of suspected persons
- Authorizing the conduct and use of covert human intelligence sources (informants)
- Acquisition of relevant categories of communications data

Such approaches should only be utilized by appropriately trained personnel and, in line with local legislative powers, the use of any intrusive investigative approach must always be proportionate, legal, accountable and necessary.

Data gathered from investigative activities can be further utilized. The Italian Medicines Agency (AIFA) has spearheaded an initiative focused on combating the theft of medicines from the regulated supply chain. This effort stemmed from incidents such as Operation Volcano,[75] which involved significant quantities of stolen medicines entering the illegal market and sometimes re-entering the regulated supply chain, posing serious public health risks. The Medi-Theft project[76] aims to establish a dedicated data-sharing and investigative platform for stolen medicines. Key stakeholders include national regulatory authorities, police and pharmaceutical companies of European Union Member States.[77] The development of a data-sharing platform aims to provide facilities for reporting, analysis and sharing of data on the reported stolen medicines from the regulated supply chain.

Initiatives such as Medi-Theft that provide a facility to gather data on the theft of medicines, whether on a national or regional basis, recognize the overall threat posed by the theft of medicines and provides an opportunity to improve understanding of the scale of theft and generate analysable data from which to build preventative evidence-based solutions.

Regulatory investigations

In addition to the possibility of initiating a criminal investigation when reports of the diversion of controlled medicines emerge, other options may exist to utilize regulatory powers to move the matter forward. Regulatory powers can be utilized to complement a criminal investigation or, depending upon local decision-making, may be the more proportionate response to the particular circumstances. Such approaches are detailed below.

Compliance investigations

Where regulatory non-compliance is identified or suspected to have been committed by a licensed entity, for example following a whistleblower report, action can be initiated by regulators to seek voluntary compliance but may also include statutory action. Where compliance is not achieved within a reasonable timescale, depending on the offence, where

[75] www.aifa.gov.it/en/-/medicrime-vs-volcano-2019.
[76] www.safe-europe.eu/project/medi-theft/index.html.
[77] https://european-union.europa.eu/principles-countries-history/facts-and-figures-european-union_en.

there is a history of non-compliance or if there is significant concern from a public health perspective, the case may still be referred for criminal investigation at any point.

Compliance visits

Where a licensed company or individual has been the subject of investigative action, follow-up unannounced regulatory compliance visits can be conducted at predetermined periods to establish if compliance is being maintained. If continued or further non-compliance is identified, this would likely lead to further enforcement action.

Risk-based inspections

A risk-based inspection programme can be utilized across the whole life span of medicine production and distribution. This approach focuses regulatory resources in areas that will maximize the protection of public health while reducing the overall administrative and economic burden to stakeholders. The risk-based approach is sharply focused upon determining that compliance is being achieved and, where necessary, providing the support to achieve satisfactory levels of compliance. Where compliance cannot be achieved or an unacceptable risk to public health exists, this process can trigger appropriate regulatory or, where appropriate, criminal enforcement action.

Resecuring the supply chain

One of the immediate priorities of the response phase following reports of the diversion of controlled medicines is to identify the source of the diversion and resecure the supply chain to prevent continuance, a key risk. With complex global supply chains involving many licensed entities, this can be a challenging objective. Actions which may assist in identifying the point of diversion might include the following.

Examination of seizures of suspected diverted controlled medicines

It is important to first confirm the veracity of any suspected diverted product that has been seized. Is the product seized a legitimate supply chain product or is it a falsified controlled medicine? Achieving confirmation requires fast-track action and collaboration with external partners:

- Engagement with the manufacturer of the product seized and other actors within the supply chain
- Forensic providers to conduct analysis of the physical product and packaging, both primary and secondary

If the product is confirmed as legitimate and, at point of seizure, remains within the original primary and/or secondary packaging, it will provide the investigator with options to:

- Utilize available batch numbers and expiry dates
- Use of any serialization mechanism

Working with national medicines regulatory agencies and external partners, the use of such data can assist in identifying the movement of the relevant batches/serialized packs through the local supply chain.

Use of supply chain data

As previously highlighted, sales data can provide insight into the movement of medicines through the supply chain. This is particularly important when seeking to identify the potential source of diversion and resecure the regulated supply chain thus preventing continuance. By the application of supply chain data analysis methodology, suspicious purchasing behaviour may be identified and provide intelligence-led lines of enquiries for investigators.

This can be further enhanced through an understanding of:

- Reported levels of thefts and losses from within the supply chain
- Nature of products reported stolen or lost, i.e. only top-strength controlled medicines, identification of patterns of such events and areas of supply chain vulnerability

Through detailed analysis of both:

- The batch movement of seized products
- The wider volume of sales data from the supply chain

the investigator may generate targeted opportunities to identify the possible sites of diversion and the suspected source.

Risk management

The management of risk forms a key strategic element of all investigations related to the diversion of controlled medicines. Impact upon the healthcare system, confidence in public authorities and public safety are just some of the risks that will need to be managed during such an investigation. Dependent upon local partnership arrangements and collaboration agreements, the leadership of managing risk is likely to be undertaken by national medicine regulatory authorities or law enforcement agencies charged with leading criminal investigations. Whoever leads on risk management will require a wide source of information and support in risk identification and the development of a balanced and cohesive response.

Adopting a structured approach to risk will ensure that both:

- Operational risk assessment will be completed describing the key operational risks (see annex 3 for an example of a proposed risk assessment template).
- Having articulated the operational risks, it will then be necessary to complete a risk management plan which will set out how the risks described in the risk assessment will be managed.

The risk management plan will document what approaches can be pursued to mitigate the identified risk. An effective way of considering this is using the mnemonic RARA, i.e., what needs to be done to:

- **R**emove the risk
- **A**void the risk
- **R**educe the risk
- **A**ccept the risk

Having completed the initial risk management process at the commencement of the investigation, it is important that the process remains dynamic, recognizing new and emerging risks. Additionally, it is important that the plan is subject to ongoing monitoring and review to ensure it remains relevant and appropriate to the current and ongoing risks.

Communication

In response to high profile or high-risk cases, it may be necessary for media lines to be developed. Proactive release of information into the public arena can assist authorities to:

- Maintain public confidence in government agencies and the healthcare system, including access to the medicines
- Assist in responding to public safety concerns
- Seek support from the public

Any media lines should be developed by working with communications professionals and must be continually reviewed to ensure they remain relevant, accurate and up to date.

Publicizing outcomes

Following the outcome of investigations, the proactive use of the media within a balanced and proportionate communication strategy can further enhance the response to incidents. As part of an agreed approach with partners, the publishing of the outcome of sanctions and penalties, both criminal and regulatory, passed following a successful investigation and subsequent prosecution can be both reassuring and contribute to wider confidence-building for authorities. The strategic purpose of such publicity may serve to:

- Provide reassurance to the public
- Encourage reporting of non-compliance
- Increase confidence in the regulatory and criminal justice systems, as well as in the healthcare system
- Discourage offending or re-offending

Post-incident review, evaluation of operational practice and lessons learned

The review of incidents and the evaluation of operational practice is key to pursuing a strategy of continual business improvement and ensuring relevance and effectiveness.

The response phase provides an evidence-based opportunity to enhance practice, identify and implement lessons learned and provide assessment of the effectiveness of both strategic and tactical approaches adopted within the local plan and context.

Irrespective of whether any incident has led to post-incident reviews, it is also critical that regular assessment and evaluation of the strategic and tactical approaches adopted is conducted. A commitment to continual improvement processes and the assessment of the effectiveness of approaches adopted is key to a high performing relevant strategy.

In conducting both post-incident reviews or the assessment and evaluation of the local counter-diversion plan, each of the three key strands of this handbook should be considered, balancing the need for effectiveness with the need for ensuring availability of and access to controlled medicines for those who need them:

- Prevention:
  - Are there gaps in our preventative approach?
  - Are we reassured that our preventative approach is effective, how would we know?
- Detection:
  - Could we have detected an incident earlier?
  - Are we detecting any areas of concern through our strategy?
- Response:
  - How effective was our incident response?
  - Have we planned and worked with key partners?

Dependent upon local structures and the approaches adopted, differing forums can be used to deliver this commitment to learning and improvement. This might include:

- Multi-agency operational practice reviews
- Annual strategic threat assessments
- Debriefing investigations, both criminal and regulatory

Whichever approach is adopted, the completion of a documented record of the review, the recommendations and any decisions made should be carried out. This document will serve as the foundation for ongoing development.

RESPONSE SUMMARY

Advance planning

Proactive coordination and infrastructure to enable a swift response to diversion incidents:

- Single points of contact in place with key authorities to ensure immediate and effective communication
- Local partnership network to facilitate fast time information sharing and cooperation with relevant stakeholders
- Implementation of information and intelligence exchange processes that meet local legal requirements
- Ability to hold multi-agency response group to coordinate stakeholders
- Processes to assess the legitimacy and source of suspected diverted controlled medicines

Criminal investigation

Investigations carried out by trained personnel using appropriate legal procedures and methods:

- Investigators trained to a high standard, qualified and experienced in the relevant jurisdiction's law and procedure
- Comprehensive investigations, for example, parallel financial investigations

Regulatory investigation

Targeted use of regulatory mechanisms to monitor compliance and manage risk:

- Compliance investigations
- Compliance visits
- Risk-based inspection programme

Resecuring the supply chain

Tracing and analysing diversion within the supply chain:

- Examination/forensic analysis of seizures of suspected diverted controlled medicines
- Analysis of supply chain data
- Identification of the point of diversion from the regulated supply chain

Risk management

Risk assessment and management to support healthcare systems:

- Effective use of risk management processes
- Assessment and management of risk/impact upon healthcare system, and confidence in public authorities and public safety.

Public communications

Use of the media to maintain clear and positive communication to the public:

- Maintaining public confidence in government agencies and healthcare systems, including access to medicines
- Responding to public safety concerns
- Seeking support from the public
- Providing reassurance to the public
- Encouraging reporting of non-compliance
- Discourage offending or re-offending

Post-incident review, evaluation of operational practice and lessons learned

The response phase should be optimized by the use of evidence-based insights that will improve practice through multidisciplinary debriefings and the ongoing evaluation of operations.

Are we reassured by the approaches we have adopted?

- Prevention
  - Are there gaps in our preventative approach?
  - Are we reassured that our preventative approach is effective, how would we know?
- Detection
  - Could we have detected an incident earlier?
  - Are we detecting any areas of concern through our strategy?
- Response
  - How effective was our incident response?
  - Have we planned and worked with key partners?

4. Diversion of controlled medicines: the international drug control system and legal instruments related to pharmaceutical crime

Under the international drug conventions, States Parties are obligated to implement mandatory control measures for substances and precursors listed in the schedules of the 1961, 1971 and 1988 Conventions.[78] The key mandatory requirements for States Parties include:

- Establishing institutional infrastructure for both domestic and international drug control
- Regulating trade
- Reducing demand for drugs
- Managing drug-related criminal justice
- Facilitating international cooperation in the justice sector

To fulfil these obligations, States Parties must designate a national authority responsible for overseeing the cultivation, production, distribution, import and export of controlled substances. This authority is also required to provide annual estimates and statistical data to INCB and establish regulatory systems to monitor all stages of the supply chain.

4.1 The specific role of the World Health Organization in the international drug control system

Key functions

Within the United Nations international drug control system, WHO contributes to the implementation of the conventions by providing expertise in several key areas. Under the 1971 Convention on Psychotropic Substances, Member States are encouraged to base prevention, treatment and rehabilitation measures on WHO recommendations and to take WHO guidance into account when establishing labelling requirements for psychotropic substances. While WHO does not directly regulate access or diversion control, it plays an important supporting role by providing normative guidance, technical tools and capacity-building resources to

[78] www.unodc.org/unodc/en/commissions/CND/Mandate_Functions/index.html.

help Member States develop balanced policies that improve access to and the availability of controlled medicines, while preventing diversion and non-medical use.[79]

The contributions of WHO in these areas are reflected in the following programmatic and advisory activities:

- The Expert Committee on Drug Dependence, which recommends changes in the scope of control of substances to reduce the risk to public health as guided by the provisions in the drug conventions, the risk of abuse and to ensure medical availability
- Promoting the initiation and strengthening of national and international programmes for the assessment, scheduling, control and appropriate use of narcotic drugs and psychotropic substances, including those of plant origin, and supporting such programmes by the development of appropriate guidelines
- Working with Member States and partners to ensure appropriate access to necessary pharmaceuticals for uses such as pain management and provide guidelines for healthcare professionals and policymakers on the supply and use of controlled substances based on research and consideration of local contexts
- Strengthening the coordination between WHO programmes relating to drugs and psychotropic substances, dealing with drug policy and management, and other related programmes
- Strengthening collaboration with interested non-governmental organizations
- Considering the relevant resolutions of governing bodies

Supporting access and preventing diversion

WHO also advocates for balanced policies and programmes that ensure equitable access to essential controlled medicines for those in need while minimizing the risks of misuse and diversion. The World Health Assembly has repeatedly highlighted the public health imperative of access to controlled medicines through multiple resolutions. These resolutions stress their importance in palliative care, emergency and essential surgical procedures, and mental and neurological disorders.[80]

In addition, as part of its mandate, WHO conducts ongoing evaluations of all medicine safety and efficacy, updating the WHO Model List of Essential Medicines to reflect current needs.

To strengthen access, WHO partners with countries on initiatives such as monitoring medicine availability and pricing at healthcare facilities, improving forecasting and supply planning, training healthcare providers on appropriate prescribing and dispensing, and developing balanced legal and policy frameworks.

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[79] 1971 Convention on Psychotropic Substances: www.incb.org/documents/Psychotropics/conventions/Commentary_on_the_Convention_1971.pdf.

[80] WHA67.19 (2014) – Strengthening of palliative care as a component of comprehensive care throughout the life course: https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R19-en.pdf.
WHA76.4 (2023) – Integrated emergency, critical and operative care for universal health coverage and protection from health emergencies: https://apps.who.int/gb/ebwha/pdf_files/WHA76/A76_R4-en.pdf.
WHA73.10 (2020) – Global actions on epilepsy and other neurological disorders: https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R10-en.pdf.

However, not all controlled medicines are used under medical supervision or for legitimate medical purposes. Their harmful non-medical use has long been recognized as a significant public health issue. As with every pharmaceutical, adverse consequences are occasionally linked to the use of controlled medicines even when administered in line with medical instructions.[81] However, unsupervised non-medical use can pose significant serious risk to human health and lives, directly harming patients, and ultimately undermining public confidence in the healthcare system.[82] Furthermore, the illegal opportunities provided by the non-medical use of controlled medicines by individuals has been recognized by criminal groups.

The involvement of organized crime groups and individual criminal enterprises at any point in the regulated pharmaceutical supply chain significantly heightens public health risks. Their activities not only jeopardize the availability of and access to controlled medicines for patients but also increase the potential for the non-medical use of these medicines and for substandard and falsified medicines, with the dangers to public health that they pose.[83]

The National Crime Agency in the United Kingdom has emphasized that advancements in technology have provided criminals with new methods and tools to exploit the pharmaceutical supply chain for the diversion of controlled medicines. This has provided various avenues for the illegal distribution of these medicines, circumventing the intended secure channels. Technology has significantly expanded the methods for committing traditional crimes and provided criminals with more sophisticated and harder-to-detect methods. Such criminal activity can undermine the cohesiveness of communities and can become pervasive as criminals illegally trade commodities without fear of detection or being reported.[84]

Organized crime groups and individual criminal enterprises are increasingly engaging in crimes involving medical products.[85] They exploit technological advances, such as the expanding capabilities of the Internet, e-commerce platforms and interconnected fast parcel services, to facilitate their illegal activities (see Figure 3).

[81] Degenhardt, L., Larance, B., Mathers, B., Azim, T., Kamarulzaman, A., Mattick, R., Panda, S., Toufik, A., Tyndall, M., Wiessing, L., and Wodak, A., on behalf of the Reference Group to the United Nations on HIV and injecting drug use. (2007). "Benefits and risks of pharmaceutical opioids: Essential treatment and diverted medication A global review of availability, extra-medical use, injection and the association with HIV". https://ndarc.med.unsw.edu.au/sites/default/files/ndarc/resources/Pharmaceutical%20opioid%20injection.pdf.

[82] Strategic Threat Assessment, Medicines and Healthcare products Regulatory Agency, 2015.

[83] www.unodc.org/documents/treaties/publications/19-00741_Guide_Falsified_Medical_Products_ebook.pdf.

[84] National Strategic Threat Assessment of Serious and Organised Crime, National Crime Agency, 2015.

[85] www.gov.uk/government/news/mhra-cracking-down-on-organised-crime-worth-200m.

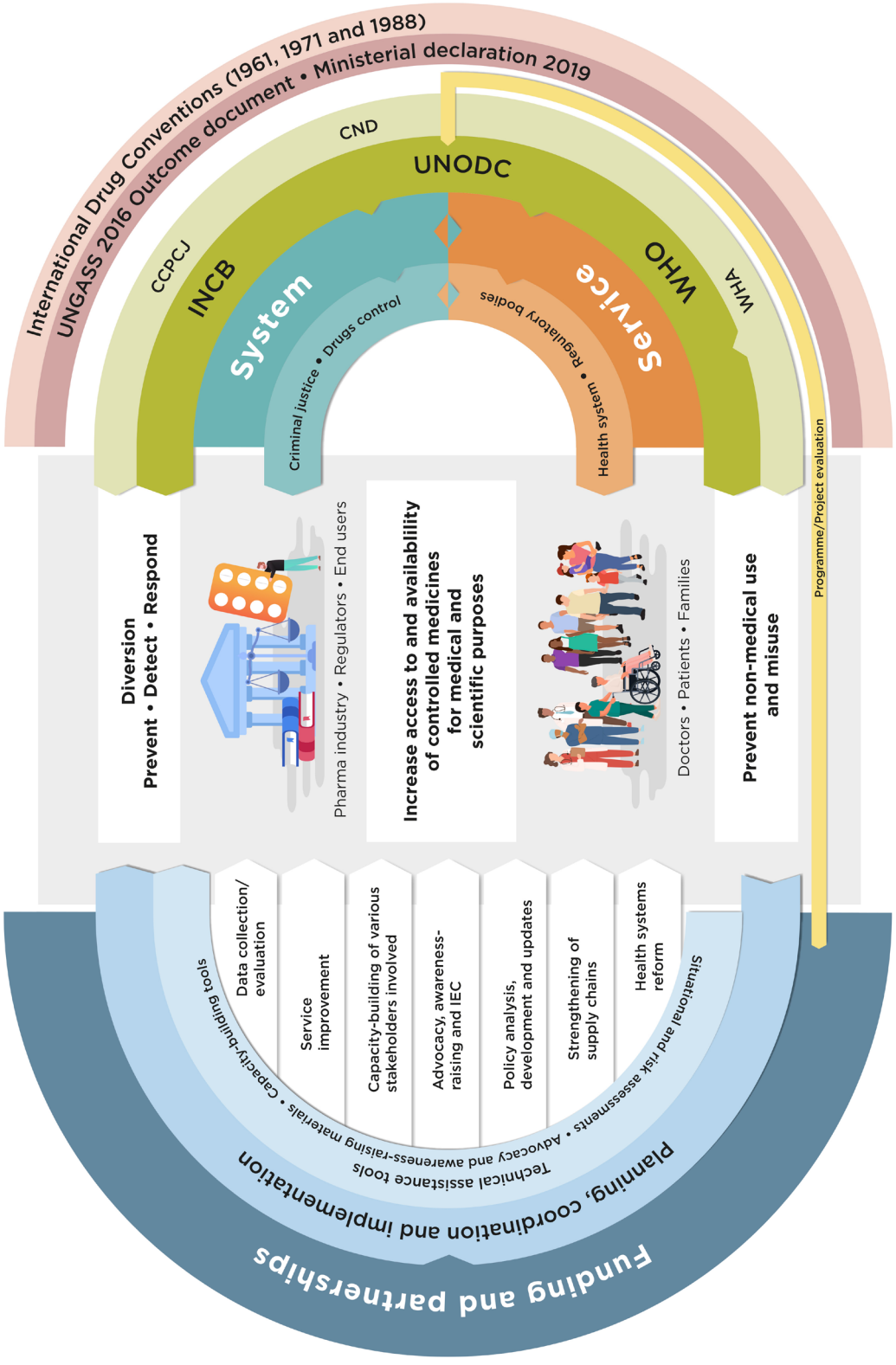

Figure 3. Programme approach to addressing availability of and access to controlled substances for medical and scientific purposes, while preventing diversion and non-medical use

4.2 Pharmaceutical crime

Pharmaceutical crime is embedded in various thematic areas of the mandate of UNODC, specifically those related to addressing the world drug problem, and preventing and combating organized crime.

Working together in partnership, they must understand these threats and develop appropriate countermeasures to mitigate the risk of diversion.

Pharmaceutical crime: the emergence of falsified controlled medicines

While not within the scope of this paper, the increasing availability within illegal markets of falsified controlled medicines purporting to be legitimate controlled medicines is an additional increasing threat. Such products are often subsequently discovered to contain undisclosed dangerous ingredients. Provisional data produced by the United States Centres for Disease Control and Prevention (CDC), National Center for Health Statistics, estimated 107,543 people died from drug overdoses in 2023.[86] These include deaths due to the use of synthetic opioids, such as fentanyl and carfentanyl, to adulterate what may appear to be legitimately manufactured controlled medicines.

Increasingly falsified controlled medicines, such as oxycodone and benzodiazepines, are being detected. Additionally, there is a growing trend whereby some of these falsified controlled medicines are found to contain dangerous synthetic opioids. The development of this illegal production and related risks was highlighted in recent research. It 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".[87]

These issues have been reported and researched within North America. A recent law enforcement case in Canada reported in the media resulted in the seizure of a total of 356,000 falsified tablets that purported to be Adderall® (dexamphetamine), Xanax® (alprazolam), Percocet® (oxycodone/acetaminophen), OxyContin® (oxycodone), and oxycodone. Subsequent forensic analysis identified that the majority of the tablets also contained carfentanyl, and a mixture of methamphetamine, benzodiazepine, heroin and MDMA.[88]

However, these threats are emerging as a wider global issue. The director-general of the National Crime Agency in the United Kingdom highlighted 284 overdose deaths in the country linked to a group of synthetic opioids (nitazene).[89] The adulteration of falsified controlled medicines presented as prescription-controlled medicines such as diazepam was a contributing factor in reported fatal outcomes providing corroboration of the findings of the United States research highlighted above.

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[86] https://blogs.cdc.gov/nchs/2024/05/15/7623/.

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

[88] https://bc-cb.rcmp-grc.gc.ca/ViewPage.action?contentId=83119&languageId=1&siteNodeId=2307.

[89] https://www.nationalcrimeagency.gov.uk/news/there-has-never-been-a-more-dangerous-time-to-take-drugs-says-national-crime-agency-as-annual-threat-assessment-is-published?highlight=WyJjeWJlcm-NyaW1lIiwib25saW5lIiwicmVwb3J0aW5nIl0=.

In Sweden, police issued a public warning ("Dangerous drug sold in fake packaging in Karlstad"[90]) to its citizens following the identification of a falsified version of a controlled medicine, Oxycontin, adulterated with a synthetic opioid called metonitazene. This product was available within local illegal markets. The alert highlighted the dangers of falsified controlled medicines and the potentially fatal consequences following ingestion.

While the undoubted risks posed by falsified controlled medicines are significant and can pose a threat to the regulated supply chain, they are not the primary focus of this paper. Guidance in relation to combating falsified medical product-related crime is available from UNODC.[91]

Pharmaceutical crime – the UNODC mandate

Addressing pharmaceutical crime is embedded in various thematic areas of the UNODC mandate, specifically those related to addressing the world drug problem, and preventing and combating organized crime. In addition, UNODC supports this important work through its Synthetic Drugs Strategy, promoting rational prescribing and access to opioids for medical and scientific use, while promoting inter-agency cooperation in addressing the non-medical use of opioids.

Additionally, UNODC highlights the priority of international law enforcement operations to disrupt trafficking and enhance operational activities to prevent the diversion and trafficking of synthetic opioids. For these reasons, it is imperative for manufacturers, wholesalers, pharmacists, healthcare professionals and government agencies, such as national medicine regulatory authorities, to work alongside law enforcement agencies. Together, they must understand these threats and develop appropriate countermeasures to mitigate the risk of diversion.

Pharmaceutical crime consists of many differing illegal activities and is defined by INTERPOL as including manufacture, trade and distribution of fake, stolen or illicit medicines and medical devices. It encompasses the counterfeiting and falsification of medical products, their packaging and associated documentation, as well as theft, fraud, illicit diversion, smuggling, trafficking and money-laundering.[92]

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[90] https://polisen.se/aktuellt/pressmeddelanden/2024/augusti/farlig-drog-saljs-i-falsk-forpackning-i-karlstad/ (in Swedish).

[91] *Combating Falsified Medical Product-related Crime: A Guide to Good Legislative Practices*, UNODC (2019).

[92] www.interpol.int/News-and-Events/News/2013/INTERPOL-and-pharmaceutical-industry-launch-global-initiative-to-combat-fake-medicines.

Annexes

1. Approaches to wholesalers highlighting areas of vulnerability to diversion

Criminal groups exploit gaps in wholesale licensing systems to infiltrate the legal supply chain and obtain controlled medicines:

- Intelligence suggests criminal groups target the legal supply chain to access controlled medicines. One area of learning where vulnerability has been identified from previous incidents has involved fraudulent use of the wholesale dealer authorization (WDA) to access pharmaceuticals, including controlled medicines. As previously highlighted, it is a requirement for an entity intending to sell or supply medicines to other licensed bodies, other than the patient using the medicine, to possess a WDA. Additionally, those purchasing pharmaceuticals, other than for dispensing to legitimate patients using the medicine, also require a WDA.
- Without a WDA, it should not be possible for those with criminal intent to purchase any type of medicines from within the regulated supply chain, except when legally able to do so at pharmacy level. The WDA contains information regarding the authorized entity including names, addresses, contact details and what restrictions or activity the WDA permits the licence holder to conduct. Such detail provides the opportunity for effective checks to be conducted on those attempting to purchase pharmaceuticals and cross reference with details provided by the purchaser and those recorded on the WDA.
- In recognition of the significance of the WDA, criminal groups seek to exploit opportunities to access and/or fraudulently utilize the authorization. The following are differing examples of ways in which rogue actors have attempted to obtain supply chain pharmaceuticals.

Fraudulent use of a wholesaler's wholesale dealer authorization without their knowledge

Licensed wholesalers' credentials may be exploited to unlawfully obtain controlled medicines without the wholesaler's awareness:

- Individuals use a WDA purchase medicine and pay using a personal bank account or credit card.
- Transaction is via email or telephone. An electronic scammed copy of the WDA is provided.
- The "customer" requests delivery to an address not named on the WDA or requests that their "driver" collects the medicines directly from the wholesaler or distributor.

A wholesale dealer authorization holder claims to export the medicines outside of the country of purchase

Some actors may falsely claim to export medicines abroad as a cover for diversion within domestic or regional markets:

- A small wholesaler buys a large amount of legitimately manufactured controlled medicines for an overseas customer.
- The WDA holder claims they are exported but no physical record that export takes place exists.
- No record of Government-issued export authorization for controlled drugs exists.

A pharmacy without a wholesale dealer authorization purchases an amount far exceeding what can be dispensed

Unlicensed pharmacies stockpile large quantities of controlled medicines for onward sale outside legal channels:

- Orders will gradually increase from 10s to 100s and up to 1,000s of packs.
- A pharmacy without a WDA cannot legally wholesale and would require a controlled drug licence to store large amounts of controlled medicines.
- The transaction is not recorded in the pharmacy's accounts.
- The medicines are then sold on to the illegal market.

Order from an overseas pharmacy or wholesaler

Suspicious international orders involve questionable licensing, upfront payment and third-party collection to obscure origin:

- An email or telephone contact arrives from company claiming to be based overseas.
- It provides a local licence of questionable authenticity.
- It expresses willingness to pay in advance for a large volume of controlled medicines.
- A bank transfer is made from a bank account in a seemingly unrelated country location.
- It requests that their nominated courier collects from the wholesaler and delivers to a shipper.

2. Examples in which licensed medicines wholesalers are commonly made victims

Wholesalers are exploited through unusual delivery requests, suspicious buyer behaviour and unverified order details:

- Last minute changes are made to consignee details.
- Requests are made for deliveries to car parks, motorway services or to other vehicles.
- The purchaser proposes collection in person from the wholesaler's premises by the purchaser.
- Unusually large quantities of medicinal products are sent to residential addresses.
- Unusually large quantities of medicinal products are sold to retail pharmacies.
- Large quantities of medicines are consigned to freight forwarders.
- There are issues that raise suspicions regarding the identity of consignee.
- The order and/or payment process does not involve the registered business contacts to whom the WDA licence refers but utilizes an individual's personal email account or payment via a personal bank account.

3. Example of an operational risk assessment template

The categories shown below provide a template for documenting investigative risks in a systematic manner, allowing each risk to categorized and assessed in terms of:

- Probability
- Impact

POLICE AND COMMUNITY CONCERNS

Assess the likelihood and potential impact of risks flagged through intelligence or local concerns:

➔ Probability of risks occurring (include details of intelligence checks conducted):

○ Low ○ Medium ○ High

➔ Impact:

○ Low ○ Medium ○ High

➔ If the risk occurs, what is likely to happen?

_____

_____

PHYSICAL RISKS

Evaluate the potential for harm or violence linked to the proposed activity:

➔ Probability of risks occurring (known risks to the public or sections thereof):

○ Low ○ Medium ○ High

➔ Risk of violence:

○ Low ○ Medium ○ High

➔ Impact:

○ Low ○ Medium ○ High

➔ If the risk occurs, what is likely to happen? Please describe

_____

_____

PSYCHOLOGICAL

Reflect on the emotional or mental strain that the situation may cause for those affected:

- Probability of risks occurring (known risk of stress to public/staff):
  - ○ Low ○ Medium ○ High
- Impact:
  - ○ Low ○ Medium ○ High
- If the risk occurs, what is likely to happen? Please describe

_____

_____

LEGAL

Determine whether the activity complies with relevant laws and regulatory frameworks:

- Probability of risks occurring (whether the activity proposed by the authorities is lawful):
  - ○ Low ○ Medium ○ High
- Impact:
  - ○ Low ○ Medium ○ High
- If the risk occurs, what is likely to happen? Please describe

_____

_____

ECONOMIC

Examine the potential financial implications for systems, services, and enforcement:

- Probability of risks occurring (known costs to investigation, wider healthcare system etc.):
  - ○ Low ○ Medium ○ High
- Impact:
  - ○ Low ○ Medium ○ High
- If the risk occurs, what is likely to happen? Please describe

_____

_____

MORAL

Consider whether the situation raises ethical concerns around justification or proportionality:

- Probability of risks occurring (whether the operation is morally justified, proportionate and necessary):
  - ○ Low ○ Medium ○ High
- Impact:
  - ○ Low ○ Medium ○ High
- If the risk occurs, what is likely to happen? Please describe

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United Nations
Office on Drugs and Crime

Vienna International Centre, P.O. Box 500, 1400 Vienna, Austria
Tel.: (+43-1) 26060-0, Fax: (+43-1) 26060-3389, www.unodc.org

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