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An analysis of Suspected Pharmaceutical and Psycho-Pharmaceutical Drug Samples: Trends in the Non-Medical Use of Pharmaceutical Substances in Sri Lanka

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Abstract: **According to the World Drug report 2024, 292 million people use illicit drugs in 2022 and it shows 20% increase over 10 years. Further, 43% of women among people who use drugs in 2022, depend on non-medical use of pharmaceutical opioids such as sedatives and tranquillizers.**

Prescription drug diversion is a major concerning challenge faced by many countries worldwide. Prescription drugs diversion involves the unlawful channelling of legitimated and regulated pharmaceuticals from legal sources to the illicit marketplace. This study was conducted by the National Narcotics Laboratory (NNL) of the National Dangerous Drugs Control Board (NDDCB) by analysing the Suspected Drug Samples received for routine analysis during the period from 2019 to 2022. These samples were referred to the NNL from various Law Enforcement and Regulatory institutions across Sri Lanka.

Sample preparation was conducted using Methanol (AR) as extraction solvent and Samples received to the laboratory was confirmed using Agilent 8890 Gas chromatograph equipped with a 5977B GC/MSD and Bruker FTIR. Of the total number of samples received in 2019, 46% of the samples were given positive identifications related to the pharmaceutical substances. Out of this samples, 14% for tramadol, 28% for Pregabalin, 1% for Methylphenidate, Acetaminophen, Alprazolam and Diazepam were identified. In 2020, 71% of the incidences received from total cases were related to pharmaceutical substances (Table 5). From this 71% of the incidences, 59% cases given positive results for pregabalin and rest of the other samples given positive results for Gabapentin, Fluoxetine, Scopolamine, Ketamine, Codeine and Tramadol. In 2021, 18% and in 2022, 24% of the cases received to the NNL were identified as pharmaceutical substances related cases. From the above identified substance, Tramadol, Pregabalin, Diazepam, Methylphenidate, Codeine and Gabapentin control under the Sri Lankan Law,

Keywords: **Narcotic Drugs, Psychotropic Substances, Psycho-pharmaceuticals, Drug Diversion.**

1. INTRODUCTION

According to the World Drug Report 2025, the number of New Psychoactive Substances (NPS) in the global drug market continues to decline and beyond the misuse of some pharmaceutical substances such as tramadol and ketamine which are not under the international control has become predominant in the global drug market (1). Further, it mentioned, some substances widely used as medicines, such as codeine, tramadol, ketamine, fentanyl, methadone and pregabalin also found in the illegal market due to some having been diverted from the legal supply and some having been illegally manufactured globally. Moreover, codeine, fentanyl and methadone are controlled under the international drug conventions, but other substances such as tramadol, pregabalin and ketamine are not controlled under the international drug conventions (1).

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International drug policy has traditionally focused on illicit drugs like cannabis, cocaine, heroin and methamphetamine. However grey and black market for pharmaceutical drugs are on the rise in many countries around the world including the Australia posing the new challenges for policy makers (1) (2).

Pharmaceutical drugs are used to treat patients in their illness. However, some drugs (Table 1) which are controlled by the Sri Lankan Acts; ***Poisons Opium and Dangerous Drugs (Amendment) Act no. 41 of 2022 and Conventions against Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, No. 01 of 2008*** are susceptible to non-medical use other than their therapeutic indication.

Table 1: Therapeutic indication of drug classes susceptible to non-medical use

Drug class	Example drug type	Example of common indication for use
Pharmaceutical opioids	Buprenorphine, codeine, fentanyl, hydrocodone methadone, pethidine, tapentadol , tramadol	Analgesia and pain relief treatment of opioid dependence
Hypnotic-sedatives	Barburates : Phenobarbital	Older class of sedatives used for treatment of insomnia and epilepsy
	Benzodiazepam : Alprazolam clonazepam,diazepam, flunitrazepam, lorazepam,midazolam, oxazepam,temazepam	Treatment of anixiety and insomnia
	Benzeodiazepine-like drugs(Z-drugs)Zopiclone, zolpidem	New class of sedatives, mainly used for treatment of insomnia
Pharmaceutical stimulant	Dexamphetamine Methylphenidate ,Phentermine	Treatment of attention deficit-hyperactivity disorder(ADHD) and for use as appetite suppressants in weight loss
PIEDs	Anabolic androgenic steroids, growth hormones, peptides	Treatment of hypogonadism,cachexia,aneamia, for muscle wasting and in testesteron therapy
Antidepressants and antipsychotics	Selected serotonin reuptake inhibitors(SSRIs)antidepresents,Fluoxitine sertraline,escitalopram Antipsychotic:Quetiapine	Treatment of depressive disorders,obsessive compulsive disorder,anxiety disorder and shizophrenia

Non-medical use of drug is defined as use of pharmaceutical drugs for non-therapeutic purposes or other than directed by registered health practitioner (3) (4).

Some instances People received the drug from legitimate health system but used for varies other reasons such as (5);

- Recreational purposes
- Experimental purposes
- To minimize negative effects of other drugs
- To substitute or combination of other drugs
- For performance enhancement

Harm related to pharmaceutical drugs are increasing global concern and common harms due to non-medical use of controlled drugs are indicated in the Table 02 (2).

Table 2: Common harm due to non - medical use of controlled drug *(4)*

Drug class	**Harm-related to non-medical use**
Opioids	• Sedation and acute intoxication • Tolerance and withdrawal with symptoms that include anxiety, craving ,restlessness, lacrimation, yawning, sweating runny nose • Fatal and non- fatal overdose • Opiod use disorder
Hypnotic-sedatives	• Sedation contributing to memory and concentration problem

	• Amnesia • Aggression,also known as Rambo effect • Tolarance, dependence and withdrawal symptoms that include headache ,depression,loss of balance, nausea,extrem anxiety,panic attacks, and insomnia as well as increased risk of seizer,tachycardia and hypertension • Mental health problems including impaired social functioning • Dependence
Pharmaceutical stimulant	• Acute cardiac events(eg,arrhythmias) • Myocardial infarction • Stroke • Chronic change to cardiovascular functioning • dependence
PIEDs	• Cardiovascular toxicity, especially atherosclerosis effects and cardiomyopathy • Psychiatric effects including mood syndrome and progression to other forms of substance abuse
Antidepressants and antipsychotics	• Seizure, confusion and psychotic -like symptoms • Sedation, combined drug toxicity with polypharmacy

Further, according to the World Drug Report 2025, the concentration of different pharmaceuticals suggests that trafficking in those pharmaceuticals is spread across different regions and there are different trafficking hubs for different substances such as fentanyl largely remains a North American Phenomenon, tramadol seizures are concentrated in Africa and codeine seizures are concentrated in Asia (1). But despite of this situation, major inequalities remain in the availability of controlled pharmaceutical opioids for medical consumption with some global population for pain relief and palliative care.

Most of the illegal drugs continues to be disproportionately used by men and according to the previous research, this gender gap in drug use is known to relate more to social, cultural and environmental factors than the biological differences. Moreover, in the case of the non-medical use of pharmaceutical opioids, stimulants as well as sedatives and tranquillizers, the proportion of women is larger in some countries and in others is almost same as that of men (1). Prevalence studies for non-medical use of drugs are scanty in Sri Lanka.

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According to the statistics in Sri Lanka, similar pattern has been observed for the drug dependency. As per Sri Lankan statistics, total number of drug-related arrests were 162,088 in 2023 and compared with 2022, it increased by 06%. Out of total, 66,142 people and 68,458 people were arrested for heroin and cannabis related offenses. In 2023, total number of direct admissions of convicted offenders were 46,939. Out of them, 29,192 have been imprisoned for narcotic offenses and 325 were females. 6 male individuals were sentenced to death. It accounts for 62.2% of all imprisonments (6)

According to the current trends related to drug abuse in Sri Lanka, cannabis is the most commonly used illicit drug and it indicated 1.9% of the total population. An estimated 0.6% of population are heroin users and approximately 0.2% of total population use pharmaceutical substances (6).

Moreover, poly drug use is common among the drug dependents. The term, ‘poly drug use’ indicates a wide range of substance combinations use either sequentially or concurrently (7). Mostly, people who use these poly drugs consume pharmaceutical substances other than their preferred drug. They use multiple drugs for a variety of reasons such as to obtain a cumulative or synergistic effect to enhance the overall psychoactive effect, a lack of availability or increase the street price of their preferred drug (7). Sometimes misuse of some pharmaceutical substances associated with self-treatment of pain anxiety, symptoms of depression, tension and sleep problems.

The non-medical use and abuse of prescription pharmaceutical drugs, cause serious public health problem. Prescription drug abuse generally describes as a use of a medications without prescription or misuse of prescription prescribed by the medical officer or physician.

Prescription drugs or psycho-pharmaceutical diversion involves the unlawful channelling of legitimated and regulated pharmaceuticals from legal sources to the illicit marketplace. Diversion of these pharmaceutical substances can occur at any point of original manufacturing premises, storage, distribution, import, export, sale, consumption and destruction. Moreover, diversion of pharmaceutical substances may lead to insufficient availability for legitimate purposes in medical system.

Objectives of the Study

To identify and analyse the major chemical constituents present in suspected pharmaceutical and Psycho-pharmaceutical drug samples.

2. METHODOLOGY

This study was conducted by the National Narcotics Laboratory (NNL) of the National dangerous Drugs Control Board (NDDCB). The analysis was carried out on Drug samples received for routine examination from various Law Enforcement and Regulatory institutions across Sri Lanka including Police Narcotics Bureau, Court of Law over the period from 2019 to 2022.

Population Size

During the year of 2019, 2020, 2021 and 2022 the NNL of NDDCB received total of 100, 56, 60 and 52 cases from various Law Enforcement and Regulatory institutions across Sri Lanka. The distribution of sample submission is indicated in the Table 03 bellow and, number of samples analysed for the presence of psycho-pharmaceuticals and other pharmaceutical substance related to above submissions are listed in the Table 04.

Table 3: No cases received from Law Enforcement Agencies and Regulatory institutions

Institution	No of cases			
	2019	2020	2021	2022
Sri Lanka Police / Police Narcotics Bureau	16	03	-	03
Magistrate's Courts	55	36	23	20
Special Investigation Unit, Sri Lanka Corps of Military Police	11	09	16	14
Sri Lanka Custom	07	04	07	03
Other	11	04	14	12
Total	**100**	**56**	**60**	**52**

Table 4: Total No. of samples analysed during 2019 to 2022

Institution	No of Samples			
	2019	2020	2021	2022
Sri Lanka Police / Police Narcotics Bureau	32	06	-	03
Magistrate's Courts	83	53	35	40
Special Investigation Unit, Sri Lanka Corps of Military Police	18	27	22	27
Sri Lanka Custom	40	08	13	03
Other	18	04	15	28
Total	**191**	**14**	**85**	**101**

All samples received were labelled and written in a registry. Further researches has followed strict chain of custody protocols of the NDDCB.

Sample Preparation

Reagents and Chemicals

Methanol (AR) was purchased from Research Lab – India and reference materials were found from Laboratory and Scientific Services division, United Nations Office on Drugs and Crime (UNODC).

Received samples were externally examined and samples with similar lot number or similar external appearance categorised in to one sample. Then representative sample taken for the analysis purpose.

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Regarding GCMS analysis, 1 milligram of the homogenized powdered sample was dissolved in 1 mL of methanol to get a solution of 1mg/mL concentration. Then sonicated for 5 minutes at room temperature and the homogenized extract was filtered through syringe filter using 0.45 µm Nylon Whatman filter units. This sample was directly injected to GC-MS.

Preparation of Standards

The stock solutions of Pregabalin, Tramadol, Codeine, and Other Substances were prepared at 1mg/mL concentration in methanol and sonicated for 5 minutes at room temperature. The homogenized extract was filtered through syringe filter using 0.45 µm Nylon Whatman filter units. The working standard solutions were stored at -4 ^{O}c when not in use.

GC-MS Analysis

Samples received to the laboratory was confirmed using Agilent 8890 Gas chromatograph equipped with a 5977B GC/MSD.

GC Conditions

HP – 5 (30m x 0.32 mm, 0.25µm) Column was used and helium uses as a carrier gas with the flow of 1.0 mL/min. Initial temperature was 60^{0}C and held for 0.5 minutes. Then temperature was increased 12^{0}C/min up to 280 ^{0}C and held for 15 Minutes. Total run time of the sample was 33 minutes and splitless mode used. Data analysis was completed using the Agilent MSD Chemstation software.

MS Conditions

Solvent delay 3 minutes and mass range was 50 to 600.

FTIR Analysis

Homogenized powdered samples were used for the FTIR analysis.

Quality Control and Assurance

Data recording and Interpretations were done by the Scientific Officers attached to the NNL of NDDCB.

3. RESULTS

According to the samples received by the NNL from 2019 to 2022, there were different types of pharmaceutical substances such as Tramadol, Pregabain, Doxylamine, Ibuprofen, Acetaminophen, Alprazolam, Methylphenidate, Diazepam, Gabapentin, Fluoxetine, Scopolamine, Loperamine, Diclofenac, Codeine and Amoxaline were identified (Figure 1).

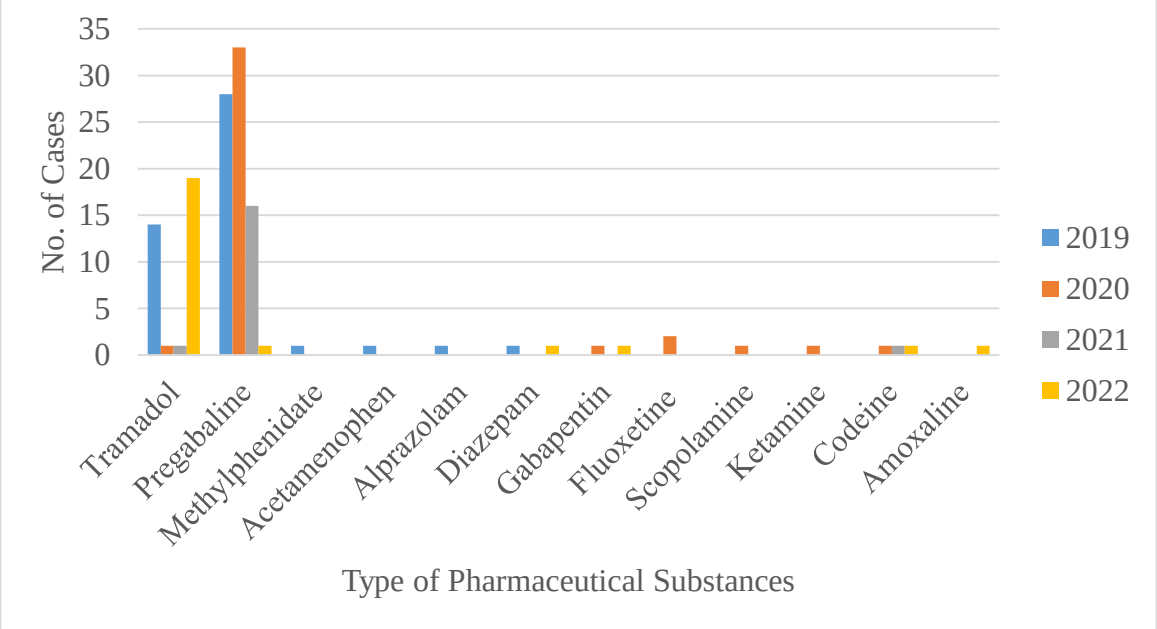

Figure 1: Pharmaceutical Substances Identified from2019 to 2022

Of the total number of samples received in 2019, 46% of the samples were given positive identifications related to the pharmaceutical substances (Table 5).

Table 5: No. of Cases received related to pharmaceutical substances 2019 to 2022

year	Total Number of Cases Received	Number of cases related to pharmaceutical substance	Percentage of confirmed cases related to pharmaceutical substance (%)
2019	100	46	46
2020	56	40	71.42
2021	60	18	30
2022	52	24	46.15

Out of this samples, 14% for tramadol, 28% for Pregabalin, 1% for Methylphenidate, Acetaminophen, Alprazolam and Diazepam were identified. Out of the total number of samples received for analysis, other 49% identified for other narcotic and psychotropic substances such as Tetrahydrocannabinol (THC), Cannabinol, Cannabidiol, Cocaine, Methamphetamine, MDMA, MDA, and MDEA and 5% of the received samples not identified for any narcotic or psychotropic substances.

In 2020, 71% of the incidences received from total cases were related to pharmaceutical substances (Table 5). From this 71% of the incidences, 59% cases given positive results for pregabalin and rest of the other samples given positive results for Gabapentin, Fluoxetine, Scopolamine, Ketamine, Codeine and Tramadol (Figure 1). Other 29% of the samples received for analysis given positive results for other narcotics such as Tetrahydrocannabinol (THC), Cannabinol, Cannabidiol, Heroin and Methamphetamine.

In 2021, 18% and in 2022, 24% of the cases received to the NNL were identified as pharmaceutical substances related cases. In 2022, out of total number of cases, 19 cases given positive results for tramadol and other pharmaceutical substances identified were pregabaline, codeine, Amoxaline, Gabapentin and Diazepam.

From the above identified substance, Tramadol, Pregabalin, Diazepam, Methylphenidate, Codeine and Gabapentin control under the Sri Lankan Law, ***Poisons Opium and Dangerous Drugs (Amendment) Act no. 41 of 2022 and Conventions against Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, No. 01 of 2008*** due to the high abuse potential and other identified pharmaceuticals such as Acetaminophen, Diclofenac Doxylamine, and Ibuprofen have not identified as the substances with abuse potential. As of these analysis, most of the incidences reported durine 2019, 2020 and 2022 related to the pregabalin and different external appearance of the pregabalin capsules were identified.

Furthermore, in the year 2020, higher number of pregabalin capsules were received to the NNL for analysis purposes and most of these incidences were reported during the COVID 19 period. Therefore, this incidence may have a relationship between COVID 19 and unavailability of the preferred drug of drug dependent individual.

4. DISCUSSION

There were multiple incidences reported related to the diversion of pharmaceutical substances since 2019 to 2022. The majority of incidences were reported related to the Pregabalin and Tramadol. By considering this emerging challenge faced by Sri Lankan society, most of these pharmaceutical substances which has high abuse potential are now controlled under the “Poisons, Opium and Dangerous Drugs (Amendment) Act, No. 41 of 2022”. Accordingly, now Tramadol, Pregabalin, Gabapentin, many benzodiazepines including diazepam, ketamine and many pharmaceutical substances with high abuse potential are controlled under the Sri Lanka Law.

In Sri Lanka, we mainly identified Pregabalin and Tramadol as the major misused psycho-pharmaceuticals. But this is not the total number of seizures done by the law enforcement agencies in Sri Lanka related to psycho-pharmaceuticals. Majority of cases reported to the Department of Government Analyst for the identification of controlled psycho-pharmaceuticals. In the year of 2022, after the new amendment of Poisons, Opium and Dangerous Drugs (Amendment) Act, most of the cases referred to the Department of Government Analyst. Further, due to the COVID 19 pandemic and due to the restriction made by the Sri Lankan government, total number of cases received to the NNL was declined.

5. CONCLUSION AND RECOMMENDATIONS

Conclusion

Analysis of suspected samples received to NNL are shown clear trend of increasing misuse and diversion of prescription medication. While Pregabalin was the most frequently detected substance Tramadol, Diazepam, Methylphenidate, Codeine, and Gabapentin were the other most commonly identified substances.

Recommendations

1. Surveillance and reporting should be strengthened to identify extend of the issue and develop mechanism to
2. Further studies are recommended to explore trends and pattern of non-medical use of controlled drugs in Sri Lanaka
3. Regulatory mechanism should be strengthened to control non-medical use of controlled drugs

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