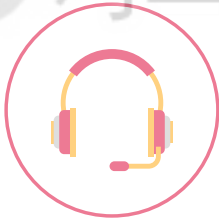


4

Reinforce Management of Controlled Drugs and Prevention of Drug Abuse





Reinforce Management of Controlled Drugs

- Set up controlled drug management system in accordance with “*Controlled Drugs Act*”
- Conduct the assessment and management of the emerging narcotics that are necessary in medical or scientific uses
- Strengthen the inspection of rational use of controlled drugs prescription
- Prevent doctors from improperly prescribing controlled drugs which may contribute to patients’ iatrogenic addiction or abuse



Enhance Anti-drug Abuse Propaganda Strategies

- Reinforce the accredited testing institutions’ capabilities in urine testing of illegal drugs
- Collect drug abuse reporting data from healthcare facilities with non-urine specimens in suspected drugs
- Plan diversified anti-drug abuse propaganda strategies, as well as promoting in workplaces, communities, online community and remote areas

Section 1 Promote Amendment to the Regulations on Controlled Drugs and Strengthen Diversion Management

Section 2 Improve the Quality of Schedule 1 and 2 Controlled Drugs

Section 3 Improve Warning and Monitoring Mechanism of Drug Abuse

Section 4 Reinforce the Propaganda of NPS Prevention and Anti-drug Campaigns

Section 5 Attainments in Development of Testing Methods for New Psychoactive Substances

04

Reinforce Management of Controlled Drugs and Prevention of Drug Abuse

TFDA has established a drug abuse monitoring mechanism to effectively manage the proper use of controlled drugs and prevent drug abuse; as well as to understand the trend of drug abuse by collecting the international and domestic information to provide to Ministry of Justice as a reference for the amendment of items of Narcotics. In addition, the Ministry of Justice places the emerging narcotics with medical and scientific uses into the “Controlled Drugs Act” for controlling to avoid improper use and abuse. TFDA has also actively acts in concert with the Executive Yuan to implement multiple anti-drug measures and strengthen anti-drug propaganda.

■ Section 1

Promote Amendment to the Regulations on Controlled Drugs and Strengthen Diversion Management

■ Introduction of the Policy

Taiwan regularly reviews and makes amendments to the regulations related to the “Controlled Drugs Act” to prevent the abuse or illegal use of controlled drugs; and to link and follow international trends

of the issue through the international interactions, while conducting audits on the distribution of controlled drugs to implement management policies.

■ Implementation Strategy

The meeting was held by the “Controlled Drugs Review Committee of the Ministry of Health and Welfare” every six months to conduct the assessment and management of the emerging narcotics that are necessary in medical or scientific uses.

Every year, a controlled drugs audit project plan is formulated to strengthen the inspection of rational use of controlled drugs prescription, and prevent doctors from improperly prescribing controlled drugs which may contribute to patients’ iatrogenic addiction or abuse, in order to maintain the drug safety of the general public.

■ Achievements and Benefits

(I) The “Controlled Drugs Review Committee of the Ministry of Health and Welfare” convened the 43rd and 44th meeting in 2021 and announced to add a total of 6 items of controlled drugs



and APIs. Under the controlled drugs audit project plan, TFDA and the local health bureaus jointly inspected a total of 234 units, of which 54 violations were found, with a violation rate of 23.08%.

(II) In 2021, 5 in-person education and training courses were conducted, namely, the “Exchange Seminar on Regulation of Controlled Drugs” in the North, Central and South regions and the “Seminar on the Use of Controlled Drugs in the Medical Educational Research and Experimental Program” in the North and South regions.

■ Section 2

Improve the Quality of Schedule 1 and 2 Controlled Drugs

■ Introduction of the Policy

In order to continuously improve product quality and expand production capacity, the Pharmaceutical Plant of Controlled Drugs, TFDA (hereinafter referred to as the Pharmaceutical Plant) initiated a number of research and development projects in 2020 and planned to bring back contract manufactured and imported products to in-house production; and the renovated plant was also started to function in 2021 to attain the goal of domestic manufacturing of sufficient supply.

■ Implementation Strategy

Newly constructed and renovated Plants are planned to add production lines for new dosage forms, with the goals to establish production lines for solutions, capsules, and patches year by year. The Pharmaceutical Plant has been remodeled to expand the production area and the storage space to better accommodate the production space. Product development is given priority to injections and solutions, followed by the capsule dosage form, and the patch types with a higher technicality level.

■ Achievements and Benefits

The Pharmaceutical Plant’s Alfentanil injection received approval from the TFDA in 2021 and has been in mass production. Meanwhile, the Pharmaceutical Plant is also engaged in establishing of solutions production line, and the research and development of oxycodone hydrochloride immediate release capsules, morphine sulfate prolonged-release capsules and fentanyl matrix-type patches. In the future, Pharmaceutical Plant will provide 5 dosage forms of self-produced products, including injections, tablets, oral liquids, capsules, and patches, reaching 70% of self-production rate. Figure 4-1 and Figure 4-2 show the solutions filling machine and automatic round bottle labeling machine of solutions production line.

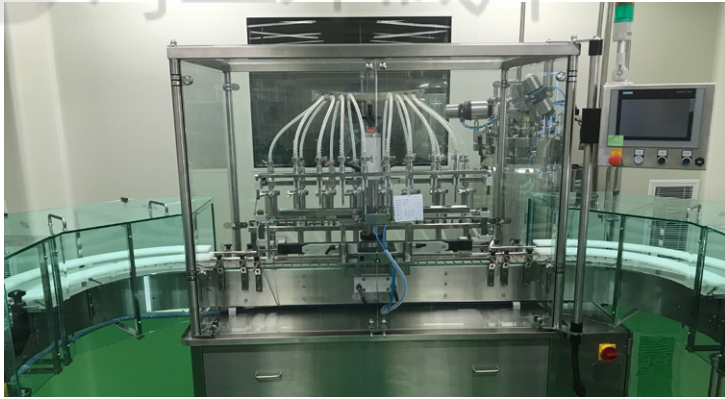


Figure 4-1 Solutions Production Line Equipment-liquid Filling Machine



Figure 4-2 Solutions Production Line Equipment-automatic Round Bottle Labeling Machine

■ **Section 3**

Improve Warning and Monitoring Mechanism of Drug Abuse

■ **Introduction of the Policy**

New Psychoactive Substances (NPS) have a wide range of varieties and develop rapidly. In order to effectively monitor the NPS, TFDA continues to reinforce the accredited testing institutions' capabilities in urine testing of illegal drugs. Meanwhile, we collect monthly drug abuse reporting data from healthcare facilities, and other statistics such as drug abuse urine sample tests, tests performed with

non-urine specimens in suspected drugs and controlled drugs cases, drug seizures, etc., then compiling into the “Drug Abuse Cases and Testing Statistics.”

■ **Implementation Strategy**

I. Drug abuse reporting mechanism for healthcare facilities

TFDA established a Drug Abuse Reporting System (DARS) to receive drug abuse cases reported monthly by healthcare facilities, in order to obtain the relevant epidemiological information of drug abuse cases.



II. Management of accredited institutions for drug abuse urine testing

In view of the increasing variety of abused drugs in recent years, TFDA completed the amendment of the “*Regulations Governing Accreditation and Management of Drug Abuse Urine Testing and Medical Institutions*” on June 30, 2021. The regulations implemented on July 1, 2021, and started to accredit the institutions replacing the original item-by-item accreditation mechanism, in order to improve the flexibility of the system and to quickly complete the testing volume, thus prevent and curb abuses.

III. Non-urine (drug) testing and reporting of drug abuse

According to the division of labor in drug testing of the Ministry of Justice, there are 15 institutions in Taiwan at present to help prosecution, police, and investigation authorities test non-urine specimens for drug abuse. In accordance with Article 9-3 of the “*Enforcement Rules of Narcotics Hazard Prevention Act*,” each inspection agency and institution should report drug test results to the Urine Test for Drug Abuse Reporting System (UDARS) every month. TFDA will count the tested positive results of non-urine samples of suspected drug and controlled drugs cases on a monthly basis and to provide reference for the development of drug control strategies by various departments.

IV. Taiwan emerging department drug abuse surveillance

In 2021, TFDA continued to commission the “Monitoring Plan for NPS in Emergency Departments (ED)” to conduct expanded screening of urine samples of 150 NPS for suspected drug poisoning cases in ED of medical institutions nationwide. The results of the expanded screening can be the reference to diagnosis and treatment for ER physicians, as well as to understand the drug abuse situation from the medical sides.

▪ Achievements and Benefits

I. Reporting situation of drug abuse from healthcare facilities

According to the DARS data, there were 28,785 cases reported for drug abuse by healthcare facilities in 2021, an increase of 13.1% comparing to 2020. The top three types of drug abuse cases were heroin (15,574, 54.1%), (meth) amphetamine (12,598, 43.8%) and benzodiazepines (1,276, 4.4%), with the similar trend as in 2020.

II. Reporting situation of accredited institutions for drug abuse urine testing

As of the end of 2021, there are 17 accredited institutions and 2 health bureaus, 14 of which can conduct NPS urine testing and report the test results to UDARS every month. TFDA continues to encourage private testing institutions to apply for accreditation and submit the

NPS testing methods validation data for review in order to expand urine testing capacity for NPS, hence protecting the citizens' health.

In 2021, a total of 221,666 urine tests were conducted in Taiwan, of which 56,705 were tested positive and accounts for 25.6% of the total number of the test. The top three drugs detected were methamphetamine, morphine and ketamine. Compared with the number of urine tests in 2020, the percentage of methamphetamine and ketamine decreased by 4.9% and 32.6%, while cases of morphine increased by 68.5%.

III. Reporting situation of drug abuse non-urine (drug) tests

In 2021, there were a total of 258,358 cases with positive test results in non-urine specimens of suspicious drug and controlled drugs cases in Taiwan, a decrease of 18.6% compared with in 2020. Of which, 29,600 were methamphetamine cases, 14,816 were ketamine cases, and 15,769 were heroin cases.

IV. Taiwan emerging department drug abuse surveillance result

In 2021, a network of 131 collaborating hospitals and expanded urine sample screening platform for 150 NPS were established. 3,303 samples were collected with tested positive cases of 1,013 or 30.7%. The final number of tested positive cases was 858 when excluding 155 cases in which the detected drugs were the same drugs prescribed by

the physicians. Of the 858 cases, males accounts for the majority; in terms of the age group distribution, 25-34 years old was the majority, followed by 35-44 years old, and then 45-54 years old. There were 32 NPS items detected, with the synthetic cathinones being detected the most, showing the same pattern as in 2020. Mephedrone was the most detected drugs, followed by Ketamine, then by 4-Methyl-N,N-DMC.

■ Section 4

Reinforce the Propaganda of NPS Prevention and Anti-drug Campaigns

■ Introduction of the Policy

To propagate drug abuse prevention, TFDA integrated professional knowledge, online media, fun games, and local resources to plan diversified anti-drug abuse propaganda strategies, as well as promoting in workplaces, communities, online community and remote areas.

■ Implementation Strategy

I. Fun in Preventing Drug Abuse

TFDA collaborated with the Ministry of Justice, the Ministry of Education and the National Police Agency of the Ministry of the Interior to implement the “Fun in Preventing Drug Abuse” program. From March 1 to December 31, 2021, the program toured Chiayi County, Chiayi City, Tainan City, Kaohsiung City, Pingtung County, and Penghu County which are under TFDA's

responsibility. TFDA utilized anti-drug operation tour display boxes, X-shaped display rack teaching aid boxes and large game equipment to promote the program at communities, workplaces, high-risk sites, campuses, etc., providing the public with rich knowledge on anti-drug policies and the information for help.

II. Prevention of drug abuse in aboriginal tribes

In 2021, TFDA reached out to the aboriginal tribes in the eastern part of Taiwan to conduct training courses and lectures for drug abuse prevention talents, training locals with local teachers in order to enhance the drug abuse prevention capacity of the aboriginal tribes.

III. Online game for anti-drug promotion

In light of young adults having high usage of online social media, TFDA consolidated resources of games, online social networks, and new media, and

incorporated narcotic hazard prevention and anti-drug self-defense 5 techniques, to launch an online game named “I’m proud that I’m anti-drug, let’s fight against drug” (Figure 4-3) to help players understand the danger of drugs and learn the skills to refuse drugs through a gopher game (Figure 4-4).



Figure 4-4

Game Promotion Information



Figure 4-3

“I’m proud that I’m anti-drug, let’s fight against drug” Online Game

▪ Achievements and Benefits

I. Fun in Preventing Drug Abuse

In 2021, TFDA implemented the “Fun in Preventing Drug Abuse” program to provide the public with of abundant education and information about anti-drug through scientific and practical cases and anti-drug touring display boxes with large game equipment. 273 promotion tours were organized in 6 cities and counties, benefiting 30,111 people.

II. Prevention of drug abuse in aboriginal tribes

In order to improve the knowledge of preventing drug abuse in the aboriginal tribes, TFDA reached out to the tribes in 2021 to hold 5 sessions of drug abuse prevention courses and train 108 trainers. Through the 10 trainers, TFDA was able to organize 28 educational sessions within the aboriginal tribes, benefiting 716 people, earned supports and affirmation from the tribe communities (Figure 4-5).

III. Online game for anti-drug promotion

From July 14 to August 13, 2021, TFDA launched “I’m proud that I’m anti-drug, let’s fight against drug” lucky draw online game; and recruited two popular internet celebrities among young people, Ling Xiao-Lu and CaoTun Boys, to post messages for propagating. The campaign attracted 13,095 participants and the posts achieved 534,258 total reach.

■ Section 5

Attainments in Development of Testing Methods for New Psychoactive Substances

▪ Introduction of the Policy

The outlaws keep rolling out new substances by imitating and modifying the chemical structures of the controlled drugs so as to evade the law control. Since the problem of NPS (new psychoactive substances) abuse comes up incessantly and becomes a concerned issue,



Figure 4-5 Aboriginal Tribes’ Drug Abuse Prevention and Control Campaign



actions should be taken immediately to prevent the worsening situation.

▪ Implementation Strategy

I. Promote experience sharing on NPS combating and drug testing techniques

With the supports of Asia-Pacific Economic Cooperation (APEC), TFDA hosted the “2021 APEC International Workshop on Food Adulterated with Drugs and Illegal Products” from August 10th to 11th, 2021. The invited representatives, scholars, and experts from France, Belgium, Australia, Taiwan, etc. shared their experiences on-line for the latest testing techniques.

II. Enlarge the applicability of drug testing

TFDA established its own database to break the constraints of insufficient spectra of the built-in database of hand-held Raman spectrometer which a total of 2,191 spectra of NPS and controlled drugs were established. TFDA also established and uploaded 819 chromatographic mass spectra of reference standards to UDARS as reference for the drug testing laboratories.

▪ Achievements and Benefits

I. Promote experience sharing on NPS combating and drug testing techniques

TFDA devotes efforts to cooperating with the local health agencies, Customs

Administration, and law enforcement agencies. The current information for international prevalence of NPS, drug testing techniques, and future challenges is shared through the workshops to master the latest transnational crime patterns and precautions for drugs, as well as improve the combating strategies of drugs in Taiwan.

II. Enlarge the applicability of drug testing

The national laboratory of TFDA has been actively enhancing the efficacy of drug testing which the GC-MS and LC-MS/MS have been utilized in assisting the identification of seized cases. The established Raman spectra database was applied in the inspection of drugs for the border and shared with the law enforcement agencies to help combat the drug trafficking. “The library of Raman Spectra: Abuse Drugs (I)” (Figure 4-6) has been published to inspire the response and attention for public anti-drug actions so as to engage the effectiveness of drug combating.



Figure 4-6

Book of “The library of Raman Spectra: Abuse Drugs(I)”