



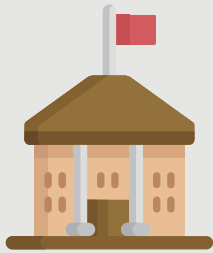
Reinforced Management of Controlled Drugs and Prevention of Drug Abuse

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New-generation Anti-drug Strategy

Two Core Sub-Strategies about drug monitoring



Drug Abuse monitoring mechanism System



New Psychoactive Substances and Drugs Abuse Information

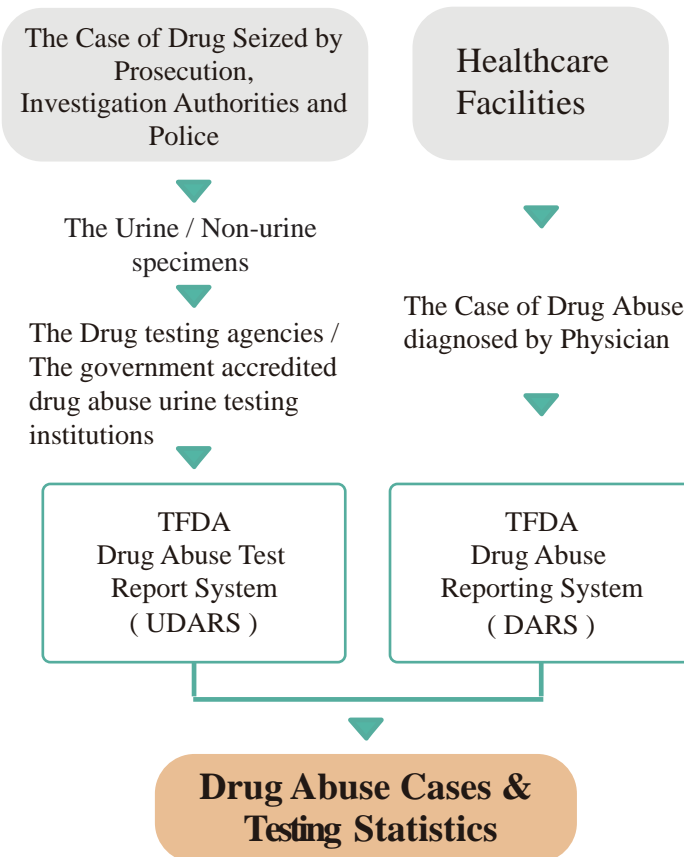
1 Prevention against the importation of illicit drug raw materials in the name of the active pharmaceutical ingredient

Three lines of defense

- the first line of defense : Customs increase the check ratio of imported raw materials.
- the second line of defense : Requirement F04 would be established that spontaneous application for importation checks should be applied for in compliance with the Regulations for the Inspection and Examination of Imported Medicaments for active pharmaceutical ingredients.
- the third line of defense : Strengthen the inspection of raw materials in pharmaceutical factories, High-risk active pharmaceutical ingredient control.

2 Expand inspection capabilities to detect emerging drugs by establishing standard analytical profiles for them

- Established the new substance magnetic resonance (NMR) testing mechanism.
- Illicit drugs and new substances collected and the mass spectrometer database with standard items created.
- Organizes the referral program for laboratories to perform urine tests for new illicit drugs.



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Reinforced Management of Controlled Drugs and Prevention of Drug Abuse

For addictive narcotics and substances with psychotic effects and their products, there is the “*Narcotics Hazard Prevention Act*” in our country to strictly govern their use. Those with medical or scientific research value, however, are listed as controlled drugs. To effectively govern the reasonable use of controlled drugs and to prevent against drug abuse, the Administration established the drug abuse monitoring mechanism that helps with an understanding of the trends of drug abuse in our country and the evaluation of new psychoactive substances (NPS) that have been abused internationally or recently. We also provide the Ministry of Justice with advice on the addition and revision of items listed as controlled at the same time. In addition, to reinforce the management of controlled drugs, when it is necessary to use NPS that are newly included in the controlled list by the Ministry of Justice over the past few years to fulfill scientific needs, such drugs will be regulated as controlled drugs in order to prevent unjustified usage or abuse that is hazardous to national health.

The Administration has cooperated with Executive Yuan to promote “New-generation Anti-drug Strategy” for the general public to get an understanding of the government’s determination to and the action it has taken to fight against drug abuse, the Administration set up the “New-generation Anti-drug Strategy” section on its official website to periodically provide the latest information on drug testing, monitoring, analysis, and drug hazards and also to educate people on staying away from drugs. Meanwhile, the anti-drug hackathon competition had all the experts in civil to brainstorm and come up with anti-drug technological and digital services.

Section 1 Assessment and Addition of Regulated Controlled Drugs Products

Origin of Policy

In order to eradicate abuse or illegal use of controlled drugs, according to the “*Controlled Drugs Act*,” the Ministry of Health and Welfare set up the “MOHW Controlled Drug Review Committee” to perform classified and itemized reviews reflective of the habits, dependency, extent of abuse, and hazards to society associated with controlled drugs and report the results to the Executive Yuan for approval and announcement.



Implementation Measures

In order to reinforce the management over controlled drugs and to prevent them from entering the market and trigger abuse, the Administration convenes the “MOHW Controlled Drug Review Committee” once every six months to assess the necessity to include emerging substances that have been abused internationally or recently under control. We also provide the Ministry of Justice with advice on the addition and revision of items listed as controlled at the same time.

The 35th and 36th MOHW Controlled Drug Review Committee had been held on June 21, 2017, and December 19, 2017, respectively to discuss listing of emerging drugs recently included by the Ministry of Justice under control that is needed for scientific purpose as controlled drugs and classifying them accordingly. Then, they are reported to the Executive Yuan according to the administrative procedure for the latter to announce their listing under control.

Outcomes and Benefits

A total of 14 controlled drugs were announced to have been added or revised in 2017. Detailed items and classes they belong to are shown in Table 4-1. None of the controlled substances mentioned above have been approved for use medically in the country at the moment. To meet scientific needs, they are listed as controlled drugs reflective of their existing classes as drugs for reinforced management over their whereabouts and for preventing against misuse or abuse that jeopardize national health.

Table 4-1 2017 Addendum to Classification of Controlled Drugs

Date of amendment	Schedules	Promulgate the names of the controlled drugs	Descriptions
January 5	Schedule 2	Methoxymethamphetamine or MMA, including 3 isomers (<i>i.e.</i> 2-MMA, 3-MMA and 4-MMA)	CNS stimulant, a type of Amphetamine chemical synthetics.
January 5	Schedule 2	2-Methylaminopropyl, Benzofuran or MAPB, including 6 isomers (<i>i.e.</i> 2-MAPB, 3-MAPB, 4-MAPB, 5-MAPB, 6-MAPB and 7-MAPB)	
June 23	Schedule 2	Chloromethyl carbamazone 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone, Alpha-PVP	CNS stimulant, a type of Cathinone chemical synthetics.
December 13	Schedule 2	Bromomethcathinone (BMC) or Methyl- α -pyrrolidinohexiophenone (MPHP), including 3 isomers (<i>i.e.</i> 2-MPHP, 3-MPHP and 4-MPHP)	

Reinforced Management of Controlled Drugs and Prevention of Drug Abuse

Date of amendment	Schedules	Promulgate the names of the controlled drugs	Descriptions
January 5	Class 3	Methoxyethylamphetamine, methoxy-N-ethylamphetamine or MEA, including 3 isomers (<i>i.e.</i> 2-MEA, 3-MEA and 4-MEA)	CNS stimulant, a type of Amphetamine chemical synthetics.
January 5	Class 3	Fluoroamphetamine (FA)	
January 5	Class 3	5-Methoxy-N-methyl-N-isopropyltryptamine (5-MeO-MIPT)	
January 5	Class 3	Butylone or bk-MBDB	CNS stimulant, a type of Cathinone chemical synthetics.
June 23	Class 3	Methyl- α -ethylaminopentiophenone (MEAPP), including 3 isomers (<i>i.e.</i> 2-MEAPP, 3-MEAPP, 4-MEAPP)	
June 23	Class 3	2-(Dimethylamino)-1-(3,4-methylenedioxyphenyl)-1-butanone, Dibutylone, Methylbutylone, bk-DMBDB	CNS stimulant, a type of cannabis active substances.
June 23	Class 3	Methyl-N-((1-(5-Fluoropentyl)-1H-indazol-3-yl)carbonyl)valinate (5-Fluoro-AMB)	
December 13	Class 3	(Methyl- α -methylamino-valerophenone, Methylpentadone or MPD, including 3 isomers (<i>i.e.</i> 2-MPD, 3-MPD and 4-MPD)	CNS stimulant, a type of Cathinone chemical synthetics.
December 13	Class 3	3,4-methylene bisoxyphenyl ethylamine pentanone [1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone, N-ethylpentylone, Ephylone]	
December 13	Class 3	Chloroethcathinone, CEC or Chloro-N-ethylcathinone, including 3 isomers (<i>i.e.</i> CEC, 3-CEC and 4-CEC)	

Section 2 New Constructions and Renovations of Pharmaceutical Manufacturing Facilities for Controlled Drugs

Origin of Policy

Existing manufacturing facilities where controlled drugs are manufactured of the Administration have been in use since 1988. The obsolete premises and equipment and also space is no longer sufficient for use. In order to meet international PIC/S GMP regulations and increase production lines and productivity that help prevent against risk of shortage in Class 1 and Class 2 controlled drugs and also to take into consideration the need for increasing the R&D space to add items to be manufactured and to increase the local production rate, the Administration raised NTD 494 million for the Controlled Drug Manufacturing Premises Construction and Renovation Project that started in 2012 and would be completed in March 2019.

Implementation Measures

In order to build such a national manufacturing facility, during as early as the planning stage, expertise of the Administration in PIC/S GMP, medicinal product manufacturing regulations, professional process equipment and requirements for the clean area and the expertise of the handling agency, that is, the Construction and Planning Agency in building and spatial design, have combined the review of construction devices, greening and energy-saving, smart buildings, among others. Meanwhile, we worked closely with design, construction surveillance, earthwork, air-conditioning, and water system service providers so that the project could be completed as scheduled in July 2017 (Figure 4-1).

Outcomes and Benefits

Respective systems, pharmaceutical equipment, and machines are being qualified in the newly built facility at the moment. Once the whole building is completed and the whole facility is PIC/S GMP certified, it is expected that the total area of all premises, old and new, of the manufacturing facility for controlled drugs, will increase by 2.3 folds; the number of production lines for injections and tablets will increase from 1 to 2. There will be reserved room for the R&D and production of oral solutions and patches to be added if needed. Production items may be expanded and added and productivity will be enhanced to ensure steady supplies of such medicinal products that are needed during wartime and in case of emergency. In addition, this new manufacturing facility was awarded “excellent” in the Public Construction Gold Award (Figure 4-2) and also the first project of the Ministry of Health and Welfare to win that award.



Figure 4-1 New manufacturing facility for controlled drugs



Figure 4-2 The 17th Public Construction Gold Award

Section 3 Domestic Drug Abuse Investigation

Origin of Policy

Drug abuse jeopardizes the national health and undermines social order; it has become an important social and public health issue. To effectively prevent against drug abuse, the Administration has created a drug abuse monitoring mechanism to help collect drug abuse incidents reported through healthcare facilities and other statistics such as drug abuse urine tests, tests performed with non-urine specimens in suspicious drug and controlled drug cases and uncovered drugs. After analysis and compilation, the monthly “drug abuse cases and tests statistics” is prepared and provided to respective ministries, departments and health authorities throughout the country for their reference.

In light of the fact that NPS are getting more and more popular, in order to monitor and prevent against abuse of NPS concurrently with the international society, the Administration started this year to compare and contrast NPS reported through the “United Nations Office on Drugs and Crimes Early Warning Advisory System” and the items detected by and reported by drug authentication institutions throughout the country through the Administration’s “Drug Abuse Test Reporting System” in order to reflect the status of abuse of such NPS in the country and related statistical charts such as “National detected status of NPS” to serve as reference while anti-drug strategies are being stipulated in Taiwan.

Implementation Measures

1. Reporting mechanism for healthcare facilities on drug abuse

Healthcare facilities are encouraged to report patients they receive with inappropriate or excessive use of addictive substances. The information to be reported includes the type, consumption method and where it is acquired, among others. The abuse information is reported to the Administration's "Controlled Drug Abuse Reporting Information System" on a monthly basis.

2. Management and reporting of approved institutions for drug abuse urine tests

Article 33-1 of the "Narcotics Hazard Prevention Act" requires and authorizes that the former Department of Health to stipulate and announce the Regulations Governing Accreditation and Management of Drug Abuse Urine Testing and Medical Institutions, the Regulations Governing Drug Abuse Urine Testing Operations and the Standards Governing the Drug Abuse Urine Testing Laboratories Established by Government Agencies in 2003 in order to specifically govern management of drug abuse urine testing and medical institutions and improve quality of tests performed at such institutions.

In order to enhance the quality of drug abuse urine tests performed by approved institutions, 15 of them were routinely accredited in 2017 and 10 were inspected from time to time. In addition, routine performance tests occurred once a quarter and four times in total per institution and 56 times combined for the approved institutions.

Testing institutions report test results periodically, on a monthly basis, to the Administration's Drug Abuse Test Reporting System for the Administration to produce the monthly statistics.

3. Non-urine (Drug) testing and reporting upon drug abuse

There are many institutions throughout the country at present to help prosecution, police and investigation authorities test non-urine specimens for uncovered drugs. According to the division of labor in drug testing under the Prosecutors Office for Taiwan High Court, by the end of 2017, there had been 8 drug testing institutions in northern, 1 in central, 3 in southern and 1 in eastern parts of Taiwan. The Administration produces statistics of positive results with non-urine specimens for suspicious drug and controlled drug cases on a monthly basis and provide it to respective ministries and departments for their reference.

Outcomes and Benefits

1. Drug abuse reporting status at healthcare facilities

The analysis data of the Controlled Drug Abuse Reporting Information System showed a headcount of 30,350 users in total reported for drug abuse by healthcare facilities throughout 2017. The headcount of people for the first three types of drugs abused was 16,062 for heroin (52.9%), 8,914 for methamphetamine (29.4%), and 1,547 for ketamine (5.1%). The headcount of users of heroin and that of methamphetamine reported in 2017 increased from those in the previous two years.

2. Reporting status of approved institutions for drug abuse urine tests

As of the end of 2017, 14 institutions had been approved by the government for performing drug abuse urine tests. The approved items included morphine, codeine, methamphetamine, MDMA, MDA, cannabinoid metabolites, ketamine, and norketamine, 9 in total. For the list of institutions that may perform drug abuse urine tests and the approved items, you may visit the Administration's official website (website: <http://www.fda.gov.tw>). There was a total of 258,531 urine tests performed throughout Taiwan in 2017; among them, 70,941 were positive. The positive rate was 27.4%.

3. Reporting data of drug abuse non-urine (Drug) tests

Among the cases submitted for testing by the prosecution, policy, and investigation authorities in Taiwan in 2017, there were 131,397 with positive results with non-urine specimens for suspicious drug and controlled drug cases. Among them, methamphetamine accounted for 30,860 (23.5%), heroin 24,943 (19.0%), and ketamine 21,429 (16.3%). Mephedrone (4-methylmethcathinone, MCAT) in particular, significantly increased in the detection rate compared to the past, followed by chloromethcathinone. Among the drug cases submitted for testing by the prosecution, policy and investigation authorities, however, as far as the new psychoactive substances are concerned, cathinine accounted for a majority, with a total of 63,266 cases (such as methylone, ethylone, chloromethcathinone, etc.), followed by dissociative 21,492, tryptamine 4,110, phenethylamine 3,168, cannabinoid active substance 1,263, piperazine 89 and others 3,198. The Administration sorted out the history of NPS detected and released the information in its NPS information section to act as a reference for respective anti-drug authorities.

Section 4 Strategies for NPS Prevention

Origin of Policy

As of the end of 2017, up to 800 NPS around the world have been reported to the United Nations Office on Drugs and Crimes (UNDOC). To help understand the status of abuse with emerging drugs in the country, the Administration created a monitoring mechanism and prepares the “drug abuse cases and tests statistics” on a monthly basis and provided it to respective ministries, departments, and health authorities throughout the country for their reference.

Implementation Measures

In order to enhance anti-drug performance and to deter emerging drugs, the Executive Yuan initiated the “New-generation Anti-drug Strategy” that focuses on five aspects, namely drug monitoring, drug prevention, drug sweeps, drug rehabilitation treatment and strategies for amending laws and regulations. As the authority in charge of the anti-drug strategy, the Administration introduced, in terms of drug monitoring, the two core sub-strategies, namely “prevention against the importation of illicit drug raw materials in the name of the active pharmaceutical ingredient” and “expand inspection capabilities to detect emerging drugs by establishing standard analytical profiles for them.” Border checks and control are performed on active pharmaceutical ingredients and the capabilities in the testing of new drugs are reinforced through cross-ministerial/cross-departmental collaboration in order to block NPS so that they cannot spread in the country.

Outcomes and Benefits

In order to prevent ill-intentioned manufacturers from turning imported active pharmaceutical ingredients into precursors for producing illicit drugs, the Administration announced on October 31, 2017 that Requirement F04 would be established (to be officially announced on March 22, 2018) that spontaneous application for importation checks should be

applied for in compliance with the Regulations for the Inspection and Examination of Imported Medicaments for active pharmaceutical ingredients. In addition, Raman analyzers were purchased to test on site if imported active pharmaceutical ingredients contain illicit drugs. Meanwhile, active pharmaceutical ingredients warehoused in the field at a pharmaceutical company were inspected to confirm if they are consistent with the purchased ingredients in order to prevent illegal acts in the disguise of legal activities.

Emerging drugs are constantly changing for the past few years to make testing more and more difficult each day. In order to detect illicit drugs in real time, the Administration integrated testing resources available at the respective ministries and departments throughout the country and established the new substance nuclear magnetic resonance (NMR) testing mechanism, with 91 reference standards of illicit drugs and new substances purchased and the mass spectrometer database with 160 reference standard items created. Such testing information is shared with testing units throughout the country. The Administration concurrently organizes the referral program for laboratories to perform urine tests for emerging drugs. The Drug Abuse Test Center of the Tzu Chi University and Taiwan Advance Bio-Pharmaceutical Inc. have applied to become a laboratory for testing methcathinone in urine. In the future, proactive efforts will be devoted to extending the developed emerging drug urine test items and methods to private testing institutions to comprehensively enhance the testing capabilities throughout the country.

The Administration has created on its official website (Figure 4-3) the exclusive section for information on NPS being abused. Diversified anti-drug information is provided to make it easier for the general public to inquire about them.



Figure 4-3 New Psychoactive Substances and Drugs Abuse Information



Section 5 New-Generation Anti-drug Strategy

Origin of Policy

The Executive Yuan approved the “New-generation Anti-drug Strategy Action Framework” on July 21, 2017 that combines the five major aspects, namely drug monitoring, drug prevention, drug sweeps, drug rehabilitation treatment and strategies for amending laws and regulations of the New-generation Anti-drug Strategy for 2017 through 2020, 4 years in total to strengthen integration of functionalities across ministries and departments so that the government can propose substantial anti-drug action plans to hopefully effectively reduce derivative crimes of drug abusers, inhibit the increase in the population of new drug abusers, and protect the health of the generation.

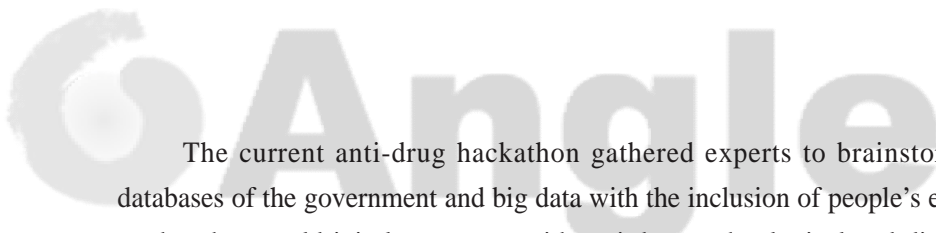
Implementation Measures

Different from traditional, serious, and dogmatic anti-drug campaigns in the past, the Administration took advantage of the open data available from related ministries and departments involved in the anti-drug operation of the government and applied the idea of citizen participation to involve people in different fields. By means of technology and digitalization, the first hackathon in the country with “prevention against illicit drugs” as its theme was organized (Figure 4-4).



Figure 4-4 2017 Anti-drug Hackathon

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The current anti-drug hackathon gathered experts to brainstorm and apply the open databases of the government and big data with the inclusion of people’s enthusiasm and creativity so that they could jointly come up with anti-drug technological and digital services in different forms, such as the Internet, APP, software and games. The Allies Day occurred in the afternoon of May 13, 2017, to clarify on the open data of the government available for the campaign and to invite non-governmental organizations to share their experience in drug rehabilitation and their experiences in fighting against illicit drugs. Then, on May 27 and 28, 2017, the two-day marathon-like collaboration began. Within limited time and space, contestants from different fields utilized anti-drug datasets and related anti-drug website resources from respective ministries and departments and developed three innovative and practical cases on the theme “prevention against illicit drugs,” including “Anti-drug Data Integration Platform,” “Illicit Drug Identification,” and “Management of Discovered Drug Abusers.”



Figure 4-5 2017 Anti-drug Hackathon

Outcomes and Benefits

A total of 32 groups registered for the contest, including families, local government grassroots employees, university and college students and representatives from society, fully demonstrating the diversity of the campaign (Figure 4-5). Participating teams were all characteristic and creative. The final 10 winning teams selected had works that included web pages that fully displayed information of drug rehabilitation centers available throughout the country, designs to help locate auxiliary therapy by searching for biological information, APPs that helped drug abusers record their feelings, data of urine test and the information about medical attention, provided users exclusive digital inquiries and reporting by Line, experienced what drug addicts really feel by playing desktop games, personal dashboards to visualize data, and RPG games to help users understand the dangers of illicit drugs.

Vice President Chen Chien-Jen presented the awards to the above-mentioned winners during the National Anti-Drug Conference on June 3 (Figure 4-6) and explained the “New-generation Anti-drug Strategy” introduced by the Executive Yuan. Non-governmental organizations, experts and scholars were invited to discuss and exchange with one another.

In addition, the Ministry of Health and Welfare has completed the Drug Rehabilitation website, through the website, people can search for drug rehabilitation institutions throughout the country. The Ministry of Health and Welfare has used it to help country-level and city-level health authorities and private institutions establish administrative resources that facilitate drug abusers return to society.



Figure4-6 National Anti-drug Conference