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Current controlled drug regulation in Taiwan

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ABSTRACT

In order to strengthen the management system of medical and scientific use of controlled drugs, Taiwan government referred to the three major drug control treaties of United Nation to formulate the "Controlled Drugs Act" in 1999. There are three kinds of system to manage controlled drugs, including (1) Schedule Management, (2) Licensing Regulation Management and (3) Diversion Control Management, such as the reporting and auditing systems. In this article, the management system of controlled drugs will be discussed thoroughly. Under the "Controlled Drugs Act", the controlled drugs are scheduled by the tendency of their habitual use, drug dependency, abuse, and social hazard. If violating the rule, the administrative sanction is applied. Cases of violations will also be given in this article.

1. Introduction

In order to strengthen drug regulation for medical and scientific purposes, Taiwan referred to the UN's "Single Convention on Narcotic Drugs in 1961", "Convention of Psychotropic Substances in 1971" and "Convention against Illicit Traffic in Narcotic Drugs and Psychotropic substances in 1988" to implement the "Controlled Drugs Act " in 1999.[1]

Having regard to the public health and social problems resulting from the rising trend of the abuse of narcotic drugs and psychotropic substance, the UN formulates the "Convention against Illicit Traffic in Narcotic Drugs and Psychotropic substances" in 1988.

In compliance with the Executive Yuan's Department of Health being changed to the Ministry of Health and Welfare, and consequently the reorganization of the Taiwan Food and Drug Administration(TFDA), Amendments were made to the "Enforcement Rules for the Controlled Drugs Act ", articles 4 and 9 of "Regulations of Rewards for Reporting the Misuse of Controlled Drugs ", "Regulations Governing the Allocation and Purchase Limitation of Schedule 1 and 2 Controlled Drugs " and "Regulations for the Issuance and Administration of Controlled Drugs Prescription Licenses and Registration License" on November 8, 2013.

2. Strategies for preventing drug abuse

Since there is a large overlap between controlled drugs and illicit drugs, drugs can be considered either controlled or illicit based on proper or improper usage. In Taiwan, there are three strategies to prevent drug abuse: "supply reduction", "demand reduction" and "harm reduction". For supply reduction, TFDA classify and mange legal drugs in order to prevent abuse and eliminate fraudulent manufacturing and illicit smuggling. The goals of "demand reduction" are to prevent first-time drug use, reduce illegal drug abuse, prevent overprescribing and misprescribing of controlled drugs, and lastly to promote drug rehabilitation. The harm of drug abuse needs to be reduced by reducing criminal rate, transmission of contagious disease, and the impacts on family and the community.

3. Regulation of controlled drugs in Taiwan

Based on the "Controlled Drugs Act" in 1999, there are four important regulations for controlled drugs in Taiwan:

(1) Enforcement Rules for the Controlled Drugs Act
(2) Regulations for the Issuance and Administration of Controlled Drugs Prescription Licenses and Registration licenses
(3) Regulations Governing the Allocation and Purchase Limitation of Schedule 1 and 2 Controlled Drugs

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(4) Regulations of Rewards for Reporting the Misuse of Controlled Drugs

The management system of controlled drugs in Taiwan has three parts, including (1) Schedule Management, (2) Licensing Regulation Management and (3) Diversion Control Management, such as the reporting and auditing systems.

1. Schedule management:

Controlled drugs are classified into four schedules based on their potential for habitual use, dependency, abuse, and danger to the society. The schedule I drug develops higher dependency, for example, heroin, morphine and opium are classified as schedule I; methadone, amphetamine are schedule II drugs; ketamine is schedule III drug; and zolpidem is schedule IV drug (Diagram 1).

A total of 7 precursor chemicals currently fall under the raw materials of controlled drugs: ephedrine, ergometrine, ergotamine, lysergic acid, methylephedrine, phenylpropanolamine and pseudoephedrine. It has been observed in recent investigations that many drug labs tend to use common cold medicines with high concentrations of ephedrine in the making of amphetamine. In order to prevent legal medicine from becoming ingredients for drug production, the Ministry of Health and Welfare has implemented regulations over the concentration, logistics, and distribution of ephedrine-based medicine packages. The ministry has also strengthened its collaboration with investigative authorities to reduce illegal use of ephedrine-based medicine, from 19 cases in 2011 to 9 in 2012, and further down to 4 in 2013, as has been reported by the Investigation Bureau.

Controlled drugs are managed by their classification, and there are differences in the intensity of management. From schedule I to III, all kinds of licenses and measures such as registration license, prescription license, controlled drugs prescription forms, cargo locks, documentation, routine reports are all required. However, for schedule IV, the prescription license, prescription form and cargo locks are not required. For schedule I and II drugs, controlled drugs manufacturing certificates are required for export or import. It is also mandatory for the manufacturing factory to apply for permission from the government. For schedule III and IV, "Batch-by-Batch Application of Import & Export Permission" and "Batch-by-Batch Application of Manufacturing Permission" are required (Table 1).

Numerous guidelines were announced by TFDA to manage controlled drugs for medical use. There are seven guidelines for addictive anesthetic, such as "Prescription handbook for cancer pain control", "Guidelines for prescribing narcotics for chronic pancreatitis patients". For sedative tranquilizers and hypnotic control drugs, "guidelines for Benzodiazepine use in sedation and hypnosis" was published by TFDA.

2. Licensing regulation management:

There are several licenses issued for different purposes:

(1) Controlled Drugs Registration License: for healthcare-related institutions;
(2) Controlled Drugs Prescription License: for individual healthcare providers, such as medical doctors, dentists and veterinarian, etc.;
(3) Permits for Importing, Exporting, and Manufacturing Controlled Drugs: for people who want to import, export or manufacture controlled drugs;
(4) Other licenses: such as Transportation license, License of Controlled Drugs used in Medical and Pharmaceutical Research.

Up until 2013, there were 14,511 controlled drug registration licenses issued.

Half of them were issued by medical clinics, and 33% were issued by pharmacies. For controlled drug prescribing licenses, over 47,391 have been issued. Of those, 87% were issued by medical doctors, and about 8% were issued by dentists. In 2013, a total of 1,563 registrations licenses, 45 import licenses, 618 permits for importing, 205 permits for exporting, and 648 permits for manufacturing were issued.[2]

3. Diversion control:

Reporting and auditing are the major strategies for diversion control of controlled drugs in Taiwan. Doctors, pharmacists, etc., are required to record in full detail the distribution of controlled drugs

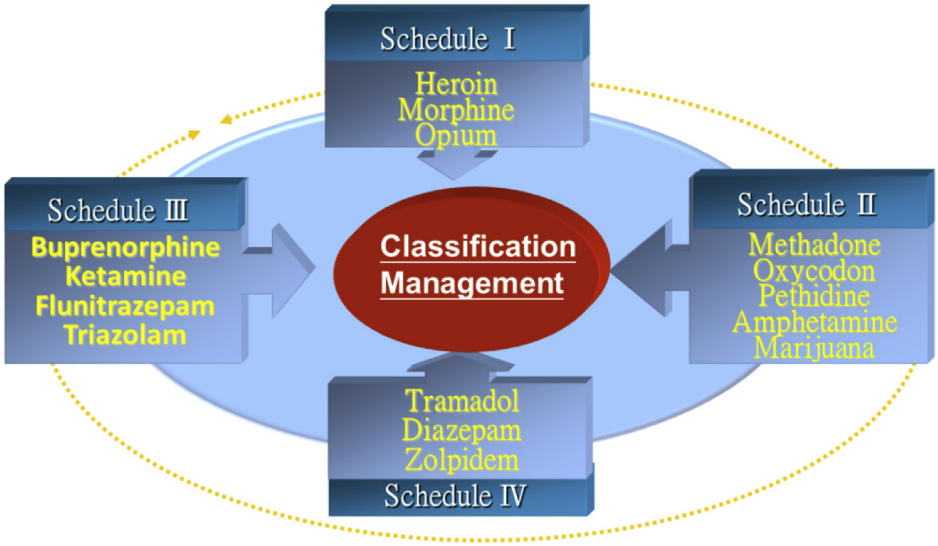

Diagram 1. Four schedules of controlled drugs.