

# **Enforcement Rules for the Controlled Drugs Act**

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1. Full text promulgated by Executive Yuan on February 23, 1944
2. Text of Article 26, 29 amended and promulgated on November 2, 1957 on Executive Yuan order (46) tainei no. 5975
3. Text of Article 9 amended and promulgated on July 3, 1959 on Executive Yuan order (48) tainei no. 3621 (Article 9 Paragraph 1 Subparagraph 10 added)
4. Amended and promulgated on February 3, 1970 on Ministry of Interior order (59) taineiwei no. 348116
5. Amended and promulgated on July 15, 1975 on Department of Health, Executive Yuan order (64) weishuyao no. 69418
6. Amended and promulgated on March 3, 1977 on Department of Health, Executive Yuan order (66) weishuyao no. 141660
7. Amended and promulgated on May 31, 1979 on Department of Health, Executive Yuan announcement (68) weishuyao no. 228227
8. Amended and promulgated on April 23, 1982 on Department of Health, Executive Yuan order (71) weishuyao no. 377194
9. Attachment 4 of Article 8 and Attachment 5 of Article 10 added and promulgated on October 29, 1984 on Department of Health, Executive Yuan order (73) weishuyao no. 500928
10. Text of Article 17, 18, 20, 23, 25, 29 and 29-1 amended and promulgated on August 18, 1993 on Department of Health, Executive Yuan order (82) weishumachu no. 8247387
11. Text of Article 29-1 amended and promulgated on January 13, 1995 on Department of Health, Executive Yuan order (84) weishumachu no. 84005159
12. Attachment 2 of Article 6 amended and promulgated on March 24, 1999 on Department of Health, Executive Yuan order (88) weishumachu no. 88014487
13. Name and text of all 38 articles of the Act originally named Enforcement Rules for the Narcotic Drugs Act amended and enforced on April 1, 2000 on Department of Health, Executive Yuan order (89) weishukuanyao no. 89016891
14. Text of Article 3, 4, 11 and 12 amended and promulgated on October 15, 2003 on Department of Health, Executive Yuan order shushoukuan no. 0920008112; Article 22-1 added; Article 6, 27 and 37 deleted
15. Full text including 31 articles amended and promulgated on June 20, 2012 on Department of Health, Executive Yuan order shushoushih no.1011800324
16. Full text including 31 articles amended and promulgated on November 8, 2013 on Ministry of Health and Welfare order shushoushih no.1021850245
17. Text of Article 20 amended and promulgated on April 24, 2018 on Ministry of Health and Welfare order weishoushih no.1071800234

**Article 1**     **These Enforcement Rules are issued in accordance with Article 43 of the Controlled Drugs Act (hereinafter "this Act").**

**Article 2**     **Institutions or business with registration licenses, whose medical or educational researchers are**

making application to dispense controlled drugs in accordance with Article 6 Paragraph 2 of this Act shall prepare said application, with a copy of documents proving identity of the researchers and relevant project materials, and submit same to the Food and Drug Administration, Ministry of Health and Welfare (hereinafter "FDA"). Applicants shall not commence the project until permission is granted by the Central Health authority.

Article 3 The prescription license for the use of controlled drugs obtained by people employed by institutions with controlled drugs registration licenses shall be kept as a record by the controlled drugs manager established by institutions in accordance with Article 14 of this Act.

Article 4 When administering Schedule 1, 2 or 3 controlled drugs, physicians, dentists shall indicate their prescription license for the use of controlled drugs number on the special prescription form. Veterinarians and assistant veterinarians shall indicate their prescription license for the use of controlled drugs number on the relevant medical records.

Article 5 The term "drugs, containing ingredients of controlled drugs, designated by physicians, pharmacists, and assistant pharmacists" as used in Article 11 of this Act shall mean drugs containing ingredients of controlled drugs that have been approved and publicly announced by the Executive Yuan in accordance with the provision of Article 3 Paragraph 2 of this Act, that also are designated drugs to physicians, pharmacists, and assistant pharmacists. However, if the ingredients of the controlled drugs fall into any to the following

categories, this Article does not apply:

1. The Executive Yuan has announced to the public that only the drugs in the form of raw materials are regulated.
2. The level of concentration or dosage falls under the limit announced by the Central Health authority.

Article 6 Medical institutions applying to dispense Schedule 1 and Schedule 2 controlled drugs for the treatment of drug addiction in accordance with Article 12 of this Act shall provide materials concerning treatment projects to the FDA along with the application, and permission must be given by the Central Health authority before the institution begins administering. However, this article does not apply in order to comply with special projects as approved by the Central Health authority.

Article 7 The term "the qualification of controlled drugs managers" as used in Article 14 Paragraph 2 in this Act is defined as follows:

1. Medical institutions: their physicians, dentists or pharmacists. However, assistant pharmacists may purchase and dispense controlled drugs that do not contain narcotic drugs.
2. Drug stores and human medicine sales: their pharmacists. However, assistant pharmacists may purchase, dispense or sell controlled drugs that do not contain narcotic drugs.
3. Medical and educational research laboratories: their full-time teachers, resident physicians, dentists, veterinarians, assistant veterinarians, pharmacists, researchers or technicians.
4. Veterinarian medical institutions and pasturage veterinarian institutions: their veterinarians or assistant veterinarians.
5. Human medicine manufactures: their

pharmacists.

6. Animal medicine manufacture and traders: their pharmacists, veterinarians or assistant veterinarians. The term "assistant veterinarians" as used in Subparagraph 3, 4 and 6 in the preceding Paragraph shall be qualified under the regulations prescribed in Article 16 Paragraph 2 of the Veterinarian Law.

Article 8 The term "permit" as used in Article 19 Paragraph 1 includes import permit and export permit.

An import permit consists of one form with five copies. The first copy is given to the exporter by the importer, and used by exporter to apply to the exporting state government. The second copy is for the importer to present to Customs. After Customs approval and signature, the importer shall return this copy to the FDA within 15 days. The third copy is kept in the files of the Customs for future reference. The fourth copy is forwarded to the exporting countries by the FDA. The fifth copy is kept in the files of the FDA for future reference.

An export permit has one form with five copies. The first copy is given to the exporter to accompany transportation of the shipment. The second copy is for the exporter to present to Customs. After approval and signature by Customs, the exporter shall return this copy to the FDA. The third copy is kept in the Custom's files for future reference. The fourth copy is sent to the importing countries by the FDA, and returned after signature. The fifth copy is kept in the files of the FDA.

Import permits and export permits mentioned in the preceding 2 Paragraph shall not be reused. The set time limit for import and export shall not exceed 6 months after the issuance date.

If the permit is not used within the set time limit it shall be returned to the FDA for cancellation.

Article 9 A person who applies to the FDA for an import permit for Schedule 1 and 2 controlled drugs in accordance with Article 19 Paragraph 1 of this Act shall prepare an application with the following documents enclosed:

1. The copy of the drug import and manufacture permit license issued by the Central Health authority, or the documents relating to the permitted medical and educational research project. However, if the copies of licenses and documents have been sent to and retained by the FDA, need not to be enclosed.
2. The records of the increase and decrease of stocks for the month prior to the date of application pertaining to the applied controlled drugs sought to be imported. However, records reported in accordance with Article 26 need not be enclosed.

Article 10 A person who applies to the FDA for the export permit for Schedule 1 and 2 controlled drugs in accordance with Article 19 Paragraph 1 of this Act shall prepare an application with the following documents enclosed:

1. The copy of drug manufacture permit license issued by the Central Health authority, or the documents of the permitted medical and educational research project. However, if the copies of licenses and documents have sent to and retained by the FDA, need not to be enclosed.
2. The documents permitting importation issued by the importing countries.
3. The records of the increase and decrease of stocks for the month prior to the date of application pertaining to the applied controlled drugs sought to be imported. However, records reported in accordance with Article 26 need not be enclosed.

Article 11 The term "permit" as used in Article 20 of this Act includes permit for importing, permit for exporting and permit for manufacturing.

Article 12 A permit for importing controlled drugs has one form with four copies. The first copy is given to the exporter through the importer, and used to handle exporting affairs with exporting countries. The second copy is for the importer to present to Customs. After approval and signature by Customs, the importer shall return this copy to the FDA within 15 days. The third copy is kept in the files of Customs for future reference. The fourth copy is kept in the files of the FDA for future reference. A permit for exporting controlled drugs has one form with five copies. The first copy is given to the exporter to go with the transportation of controlled drugs. The second copy is for the exporter to present to Customs. After approval and signature by Customs, the exporter shall return this copy to the FDA within 15 days. The third copy is kept in the files of the Customs for future reference. The fourth copy is sent to the importing countries in accordance with the provisions of international treaties or the regulations of the importing countries, and returned after signature. The fifth copy is kept in the files of the FDA for future reference. The permit for importing and exporting controlled drugs mentioned in the preceding 2 Paragraph shall not be reused. The given time limit of importing and exporting shall not exceed three months after the issuance date. If the permit is not used within the set time limit, it shall be returned to the FDA for cancellation.

Article 13 A person who applies to the FDA for a permit for importing Schedule 3 and 4 controlled drugs in

accordance with Article 20 of this Act shall prepare the application with the following documents enclosed:

1. The copies of drug import and manufacture permit license issued by the Central Health or Agricultural Administration or of the approved medical and educational research projects. However, one who has sent copies of the documents mentioned above to the FDA for references need not to enclose them.
2. The records of increase and decrease of stocks for the month prior to the date of application of the applied controlled drugs sought to be imported. However, records reported in accordance with Article 26 need not be enclosed.

Article 14 A person who applies to the FDA for a permit for exporting Schedule 3 and 4 controlled drugs in accordance with Article 20 of this Act shall prepare the application with the following documents enclosed:

1. The copies of manufacture permit license issued by the Central Health or Agricultural Administration, or of the approved medical and educational research projects. However, one who has sent the copies of the documents mentioned above to the FDA for reference need not to enclose them.
2. The records of increase and decrease of stocks for the month prior to the date of application of the applied controlled drugs sought to be exported. However, records reported in accordance with Article 26 need not be enclosed.
3. The import permit from the importing state government. The FDA may request such documents shall be authenticated by an embassy, consulate, or representative office of the R.O.C., or other institute or office authorized by the Ministry of Foreign

Affairs if necessary.

Article 15 After the controlled drugs are imported and received the confirmed importing documents sent by the importing countries in accordance with the relevant international treaties; the FDA shall note the names and quantity of the actual imported drugs on the relevant documents, provide confirming signature and return to the exporting country.

Article 16 A person who applies to the FDA for the permit for manufacturing Schedule 3 and 4 controlled drugs in accordance with Article 20 of this Act shall prepare the application with the following documents enclosed:

1. The copies of drug manufacture permit license issued by the Central Health or Agricultural Administration, of the approved medical research projects or permission documents for developing drugs. However, one who has sent the copies of the documents mentioned above to the FDA for reference need not to enclose them.
2. The records of increase and decrease of stocks for the month prior to the date of application pertaining to the applied controlled drugs sought to be manufactured. However, records reported in accordance with Article 26 need not be enclosed. The permit for manufacturing controlled drugs mentioned in the preceding Paragraph shall not be reused. The given time limit of manufacturing shall not exceed three months after the issuance date.

Article 17 The receipt containing the purchasers' signature as mentioned in Article 21 of this Act, shall contain the names, the registration numbers, addresses of purchaser and seller, date, name of products, drug permit license, name of manufacturer, ingredient



and content of controlled drugs, schedule, batch numbers and purchased amount.

The receipt in duplicate as prescribed in the preceding Paragraph, shall be retained by purchaser and seller each other. Both purchaser and seller shall record the contents and keep the receipt and record for 5 years.

Article 18 A patient who brings into the country for legitimate personal use Schedule 1, 2 or 3 controlled drugs or departs from the country with same must have a statement, along with the physician's diagnosis letter recording the name of illness, the procedure of treatment, and the reasons for treating such illness with controlled drugs and file same with the FDA for reference.

The patient's statement shall include the following items:

1. The name, birth date, residence and passport number of the patient.
2. The name, specification and amount of the controlled drugs bought in or out of the country.
3. The period of time in or out of the country.
4. The ports for entry or exit.

Article 19 To make an initial Schedule 1 and 2 controlled drugs purchase, the institutions or businesses that have obtained a controlled drugs registration license shall ask the pharmaceutical plant under the FDA as mentioned Article 4 Paragraph 1 of this Act (hereinafter " the pharmaceutical plant ") for a specimen seal impression card that has one form with two copies. After completion, one copy shall be sent to the pharmaceutical plant, and the other copy shall be kept for reference.

To purchase Schedule 1 and 2 controlled drugs, a request for the appropriate order forms shall be

made to the pharmaceutical plant. After completion, the form shall be sent to the pharmaceutical plant for processing. The seal on the order form shall be identical to the one on the specimen seal impression card as mentioned in the preceding Paragraph.

When the seal for the card for specimen seal impression as mentioned in Paragraph 1 is changed, one shall present the new card to the pharmaceutical plant, then one may continue purchasing.

Article 20 To sell Schedule 1 and 2 controlled drugs in accordance with Article 4 Paragraph 1 of this Act, the pharmaceutical plant shall hand over the drugs directly to the purchaser or send the drugs through the post office. In case that any of the following circumstances occurs, and where there may not hand over the drugs directly to the purchaser or send the drugs through the post office, after the approval of the Central Health authority, the pharmaceutical plant may entrust a logistics industry for transport or by other methods :

- 1.The drugs require special transport conditions.
- 2.When the event of natural disasters, emergencies, or mass casualty events occurs.

To deliver Schedule 1 and 2 controlled drugs required for carrying out any special projects promoted by the governmental agencies, the pharmaceutical plant shall report to the Central Health authority for approval.

Article 21 To transport Schedule 1 and 2 controlled drugs domestically, the shippers shall present to the FDA in accordance with Article 23 in this Act the following materials to apply for a controlled drugs transportation permit:

1. The name, address, the person in charge, the number of controlled drugs registration license of

the institutions or companies that ship or receive the shipment, and the name of the controlled drugs manager and the number of the manager's professional certificate.

2. The name, specification, amount and batch number of the controlled drugs to be transported.

3. The reasons for transportation.

4. The planned date for transportation.

Article 22 A controlled drugs registrant applying to destroy controlled drugs in accordance with Article 26 Paragraph 1 of this Act shall prepare an application. After such destruction, the local health administration shall issue a document confirming the destruction, and notify the FDA.

Article 23 If the loss of controlled drugs, due to mislaying, theft and other criminal cases, as mentioned in Article 27 Paragraph 2 of this Act, the scene shall be preserved and the theft immediately reported to the local police agencies, and documents obtained establishing such report. The police agencies shall have the case listed as the special criminal cases, and prioritize the investigation.

Article 24 When maintaining records in accordance with Article 28 Paragraph 1 of this Act, Human medicine or veterinary medicine manufacturers and sellers shall record the following items according to each individual drug and batch number:

1. The name of drug, the ingredients and the contained amount of controlled drugs, drug permit license number, schedule, batch number, the minimal unit, and the name of the manufacturer.

2. The records of increase and decrease of stocks, including the date, reason, amount of increase and decrease of stocks, the source of increase of stocks,

the name, address, telephone number, controlled drugs registration license number of the institutions or sellers for decrease of stocks, and the following items:

- (1) If the increase of stocks derives from import or manufacturing, the number of the permit for importing or manufacturing shall be recorded.
  - (2) If the increase of stocks derives from the seized lost controlled drugs, the number of the document for proving the seized lost controlled drugs shall be recorded.
  - (3) If the decrease of stocks derives from exporting, destruction or loss, the number of the permit for exporting and of the documents for proving the destruction or loss shall be recorded.
  - (4) If the decrease of stocks derives from manufacturing drugs, the names, batch number and the number of the permit for manufacturing of the manufactured drugs.
3. The inventory amount.

Article 25 When maintaining records in accordance with Article 28 Paragraph 1 of this Act, medical institutions, pharmacies, veterinarian medical institutions, pasturage veterinarian institutions, and medical and educational research laboratories shall record the following items for each individual drug:

1. The name of the drug, the ingredient and contained amount of controlled drugs, drug permit license number, schedule, batch number, the minimal unit, and the name of the manufacturer.
2. The records of increase and decrease of stocks, including the date, reason, amount of the revenue and expenditure, and the following items:
  - (1) If the increase of stocks derives from purchasing or transferring, the drug batch number, the name and the controlled drugs registration license number of

the providing institutions or businesses.

(2) If the increase of stocks derives from the seized lost controlled drugs, the number of the documents for proving the seized lost controlled drugs shall be recorded.

(3) If the decrease of stocks derives from destruction or loss, the number of the documents for proving such destruction or loss shall be recorded.

(4) If the decrease of stocks derives from returning the goods or transferring, the name and controlled drugs registration license number of the institutions or businesses for such decrease of stocks shall be recorded.

(5) If the decrease of stocks derives from dispensing or administering Schedule 1 to 3 controlled drugs, the name of the patient (or the number of medical record, and the name of the person responsible for the animal) and the quantity given out shall be recorded daily in details.

(6) If the decrease of stocks derives from dispensing, administering Schedule 4 controlled drugs, the daily total dispensed amount shall be record in detail.

(7) If the decrease of stocks derives from research or testing, the name, the number of document for approval of the research or testing projects and the names of the user shall be recorded.

3. The inventory amount.

Article 26 When reporting the records maintained for controlled drugs in accordance with Article 28 Paragraph 2 of this Act, the western medicine or veterinary medicine manufacturer and sellers shall report the records for the previous month to the local health administration and the FDA prior to the 20th of every month (institutions has no transaction record are included), and the records shall record the following items for each individual drug batch by

batch :

1. The name of the reporting institutions, controlled drugs registration license number, address, telephone number, the person in charge, the name of the controlled drugs manager, reporting date, the time period of the reported records, with the official seal, the seal of person in charge, the seal and signature of the controlled drugs manager impressed.

2. The name of the drug, the ingredient and contained amount of controlled drugs, drug permit license number, schedule, batch number, minimal unit and the name of the manufacturer.

3. The inventory amount of the previous time period.

4. The records of the increase and decrease of stocks of the current time period, the content of that shall be identical to the maintained records.

5. The inventory amount of the current time period. The reporting mentioned in the preceding Paragraph may be done via electronic means. The format and specification of such medium shall be announced to the public by the Central Health authority.

Article 27 When reporting the records maintained of controlled drugs in accordance with Article 28 Paragraph 2 of this Act, medical institutions, drug stores, veterinarian medical institutions, pasturage veterinarian institutions, medical and educational research and testing laboratories shall follow the following regulations:

1. Reporting Schedule 1, 2, 3 and 4 controlled drugs of the previous year to the local health administration and the FDA in January (institutions has no transaction record are included).

2. When changing the institution of person in charge or controlled drugs manager in the content of

controlled drugs registration license, the registrant shall report Schedule 1, 2, 3 and 4 controlled drugs to the local health administration and the FDA.

3. The reporting mentioned in the 2 preceding Subparagraph shall bear the following items for each individual drug:

(1) The name of the reporting institutions, controlled drugs registration license number, address, telephone number, the person in charge, controlled drugs manager of the reporting institutions, the reporting date and time period of the reported records with the official seal, the seal of the person in charge, the seal and signature of the controlled drug manager impressed.

(2) The name of the drug, the ingredients and the contained amount of controlled drugs, drug permit license number, schedule, minimal unit and the name of the manufacturer.

(3) The inventory amount of the previous time period.

(4) The records of increase and decrease of stocks of the current time period shall be identical to the maintained records. However, if the increase of stocks is resulted from returning the drugs or the decrease of stocks is resulted from dispensing, administering, researching and testing, the institutions may record only the total amount of the increase and decrease of stocks of the reported time period.

(5) The inventory amount of the current time period. The reporting mentioned in the preceding Paragraph may be done via electronic means. The format and specification of such means shall be announced to the public by the Central Health authority.

Article 28 When institutions or businesses that have obtained a controlled drug registration license, apply to

permanently suspend business because of the death of the person in charge, the closest relatives of that person may handle the transfer, destruction and reporting of the inventory of controlled drugs in accordance with the relevant regulations

Article 29 When transferring Schedule 1 and 2 controlled drugs in accordance with the provisos of Article 31 of this Act, one shall apply to the FDA for a transportation permit.

Article 30 The forms of the documents used in this Act and these Enforcement Rules shall be prescribed by the Central Health authority.

Article 31 These Enforcement Rules shall come into force from the date of their promulgation.