MINISTRY OF HEALTH ---	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness ---
No. 19/2014/TT-BYT	*Hanoi, June 02, 2014*

CIRCULAR

MANAGEMENT OF ADDICTIVE DRUGS, PSYCHOTROPIC DRUGS, AND DRUG PRECURSORS

Pursuant to the Law on Pharmacy No. 34/2005-QH-11 dated June 14, 2005;

Pursuant to the Law on Narcotic Control No. 23/2000/QH10 dated December 19, 2000 and the Law No. 16/2008/QH12 dated June 03, 2008 on amendments to the Law on Narcotic Control;

Pursuant to the Government's Decree No. 79/2006/ND-CP dated August 09th 2006, specifying the implementation of a number of articles of the Law on Pharmacy;

Pursuant to the Government's Decree No. 89/2012/ND-CP dated October 24, 2012 on amendments to the Decree No. 79/2006/ND-CP;

Pursuant to the Government's Decree No. 80/2001/ND-CP dated November 05, 2001 on guidelines for control of lawful activities pertaining to narcotics in Vietnam;

Pursuant to the Government's Decree No. 58/2003/ND-CP dated May 19, 2003 on control of import, export, transit of narcotic substances, precursors, addictive drugs, and psychotropic drugs;

Pursuant to the Government's Decree No. 82/2013/ND-CP dated July 19, 2013 on promulgation of the list of narcotic substances and drug precursors;

Pursuant to the Government's Decree No. 63/2012/ND-CP dated August 31st 2012 defining the functions, tasks, powers and organizational structure of the Ministry of Health;

At the request of the Director of Drug Administration of Vietnam,

The Minister of Health promulgates a Circular on management of addictive drugs, psychotropic drugs, and drug precursors.

Chapter I

GENERAL REGULATIONS

Article 1. Scope and regulated entities

This Circular deals with activities pertaining to addictive drugs, psychotropic drugs, drug precursors, commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, commercial combined drugs that contain drug precursors used for healthcare, analysis, testing, and scientific research by organizations and individuals (hereinafter referred to as entities) in Vietnam and overseas.

Article 2. Interpretation of terms

In this Circular, the terms below are construed as follows:

1. *Addictive drugs include:*

a) Raw materials that contain addictive ingredients listed in Appendix I enclosed herewith.

b) Semi-finished products that contain any of the addictive ingredients listed in Appendix I enclosed herewith.

c) Commercial drugs that contain any of the addictive ingredients listed in Appendix I enclosed herewith, regardless of concentration.

d) Commercial drugs that contain an addictive ingredient in combination with other active ingredients, the concentration of additive ingredients in which is higher than the level prescribed in Appendix II enclosed herewith.

dd) Commercial drugs that contain an addictive ingredient in combination with other addictive ingredients; commercial drugs that contain an addictive ingredient in combination with psychotropic ingredients; commercial drugs that contain an addictive ingredient in combination with a drug precursor; commercial drugs that contain an addictive ingredient in combination with psychotropic ingredients and drug precursors, regardless of concentration of addictive ingredients, psychotropic ingredients, and drug precursors.

2. *Finished addictive drugs are drugs specified in Points c, d, and dd Clause 1 of this Article.*

3. *Commercial combined drugs that contain addictive ingredients are commercial drugs that satisfy all requirements below:*

a) Contain active ingredients other than addictive ingredients, psychotropic ingredients, and drug precursors;

b) Contain addictive ingredients; or contain addictive ingredients in combination with psychotropic ingredients; or contain addictive ingredients in combination with drug precursors; or contain addictive ingredients in combination with psychotropic ingredients and drug precursor;

c) Concentration of addictive ingredients, psychotropic ingredients, and drug precursors does not exceed the levels prescribed in Appendices II, IV and VI enclosed herewith.

4. *Psychotropic drugs include:*

a) Raw materials that contain any of the psychotropic ingredients listed in Appendix III enclosed herewith.

b) Semi-finished products that contain any of the psychotropic ingredients listed in Appendix III enclosed herewith.

c) Commercial drugs that contain any of the psychotropic ingredients listed in Appendix III enclosed herewith, regardless of concentration.

d) Commercial drugs that contain a psychotropic ingredient in combination with other active ingredients, the concentration of psychotropic ingredients in which is higher than the level prescribed in Appendix IV enclosed herewith.

dd) Commercial drugs that contain a psychotropic ingredient in combination with other psychotropic ingredients; or commercial drugs that contain psychotropic ingredients in combination with drug precursors, regardless of concentration.

5. *Finished psychotropic drugs are drugs specified in Points c, d, and dd Clause 4 of this Article.*

6. *Commercial combined drugs that contain psychotropic ingredients are commercial drugs that satisfy all requirements below:*

a) Contain active ingredients other than addictive ingredients, psychotropic ingredients and drug precursors;

b) Contain psychotropic ingredients or psychotropic ingredients in combination with drug precursors;

c) Concentration of psychotropic ingredients and drug precursors does not exceed the levels prescribed in Appendices IV and VI enclosed herewith.

7. *Drug precursors include:*

a) Raw materials that contain any of the drug precursors listed in Appendix V enclosed herewith.

b) Semi-finished products that contain any of the drug precursors listed in Appendix V enclosed herewith.

c) Commercial drugs that contain any of the drug precursors listed in Appendix V enclosed herewith, regardless of concentration.

d) Commercial drugs that contain a drug precursor in combination with other active ingredients, the concentration of the drug precursor in which is higher than the level prescribed in Appendix VI enclosed herewith.

dd) Commercial drugs that contain a drug precursor in combination with other drug precursors, regardless of concentration.

8. *Commercial precursor drugs are drugs specified in Points c, d, and dd Clause 7 of this Article.*

9. *Commercial combined drugs that contain drug precursors are are commercial drugs that satisfy all requirements below:*

a) Contain active ingredients other than addictive ingredients, psychotropic ingredients and drug precursors;

b) Contain drug precursors the concentration of which does not exceed the levels prescribed in Appendix VI enclosed herewith.

Chapter II

DRUG SALE

Article 3. General rules

1. Manufacturers, exporters, importers, wholesalers, retailers, and providers of services pertaining to addictive drugs, psychotropic drugs, drug precursors, commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, commercial combined drugs that contain precursors must satisfy requirements for drug sale prescribed in Chapter II of the Law on Pharmacy, Chapter IV of the Government's Decree No. 79/2006/ND-CP dated August 09th 2006, specifying the implementation of a number of articles of the Law on Pharmacy, and the Government's Decree No. 89/2012/ND-CP dated

October 24, 2012 on amendments to the Decree No. 79/2006/ND-CP, and regulations in this Circular.

2. Manufacturers, exporters, importers, wholesalers, and providers of services pertaining to addictive drugs, psychotropic drugs, or drug precursors must formulate and adhere to standard operating procedures (SOP) for addictive drugs, psychotropic drugs, and drug precursors in order to administer the export, import purchase, sale, preservation, delivery, and receipt, transport, and destruction drugs. The formulation of SOP must ensure safety without any loss; each stage must be recorded in books bearing signatures for purposes of attribution of individual responsibility for each stage.

3. Manufacturers, exporters, importers, wholesalers, and providers of services pertaining to commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors must have SOPs as prescribed in Clause 2 of this Article. Such SOPs may be established separately or included in SOPs for other drugs.

4. An individual that participate in the sale of addictive drugs, psychotropic drugs, drug precursors, or commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors must be provided with training in relevant legislative documents and SOPs; training profiles must be kept at the facilities.

Article 4. Manufacture

1. Any facility licensed to manufacture addictive drugs, psychotropic drugs, and drug precursors may keep manufacturing them.

By November 30, any facility that wishes to manufacture addictive drugs, psychotropic medicines, or drug precursors shall submit an application to Drug administration of Vietnam - the Ministry of Health. Drug Administration of Vietnam shall amend the list of facilities permitted to manufacture addictive drugs, psychotropic medicines, and drug precursors.

2. Any facility that manufactures addictive drugs, psychotropic medicines, or drug precursors must comply with the following regulations:

a) Meet standards of GMP applied to each dosage form for at least 02 years.

b) With regard to personnel:

- Keepers of addictive drug warehouses must have bachelor’s degrees in pharmacy and have worked for at least 02 years for drug manufacturers.

- Keepers of psychotropic drug and precursor warehouses must have bachelor’s degrees or associate degrees in pharmacy and be authorized in writing by the head of the facility (each authorization does not last for more than 12 months).

- Employees in charge of log-keeping and reporting must have bachelor’s degrees in pharmacy and have worked for at least 02 years for drug manufacturers;

c) Records: any facility that manufactures addictive drugs, psychotropic drugs, and drug precursors must make and keep the following documents:

- A log of preparation of addictive drugs, psychotropic drugs, drug precursors using the Template No. 1 enclosed herewith.

- A log of sales, purchases of addictive drugs, psychotropic drugs, drug precursors using the Template No. 2 enclosed herewith.

- Notes of delivery of addictive drugs, psychotropic drugs, drug precursors using the Template No. 3 enclosed herewith;

3. Any facility that manufactures commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors must:

a) Meet standards of GMP applied to each dosage form for at least 02 years.

b) With regard to personnel:

- Keepers of warehouses of raw materials and semi-finished products that contain addictive ingredients must have bachelor's degrees in pharmacy and worked for at least 02 years for drug manufacturers.

- Keepers of warehouses of raw materials and semi-finished products that contain psychotropic ingredients or drug precursors must have bachelor's degrees or associate degrees in pharmacy and be authorized in writing by the head of the facility (each authorization does not last for more than 12 months).

- Employees in charge of log-keeping and reporting must have bachelor's degrees in pharmacy and have worked for at least 02 years for drug manufacturers;

c) Any facility that manufactures commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors must keep a log of delivery and receipt of such drugs using Template No. 4 enclosed herewith.

4. Any facility that manufactures addictive drugs, psychotropic medicines, or drug precursors may:

a) Buy, import raw materials and semi-finished products that contain addictive ingredients, psychotropic ingredients, or drug precursors to manufacture their drugs;

b) Export addictive drugs, psychotropic drugs, and drug precursors they manufacture.

c) Sell commercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs they produce to the facilities mentioned in Clause 1 Article 5 of this Circular.

5. Any facility that manufactures commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors may:

a) Buy, import raw materials and semi-finished products that contain addictive ingredients, psychotropic ingredients, or drug precursors to manufacture their drugs;

b) Export commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors;

c) Directly sell commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors they produce to medical facilities and drugstores that meet standards of Good Pharmacy Practice (GPP) nationwide;

d) Sell commercial combined drugs that contain addictive ingredients, combined drugs that contain psychotropic ingredients, or combined drugs that contain drug precursors to only one drug wholesaler that has the certificate of eligibility for drug business in a province, who will sell drugs to medical facilities and drugstores that meet standards of GPP within that province.

6. When a facility wishes to buy or import raw materials that contain addictive ingredients, psychotropic ingredients, or precursors for the purpose of research and development of new products, the facility shall submit an application (Template No. 05 enclosed herewith) and a report (Template No. 06 enclosed herewith) on the quantity of raw materials used for research and experimental production

Article 5. Export and import

1. The companies in charge of export, import, and supply of addictive drugs, psychotropic drugs, and drug precursors used for drug manufacturing to facilities selling or using drugs nationwide are enumerated in Appendix VII enclosed herewith.

By November 30, any facility that wishes to export or import addictive drugs, psychotropic medicines, or drug precursors shall submit an application to Drug administration of Vietnam - the Ministry of Health. Drug Administration of Vietnam shall consider the applications and submit proposals to the Ministry of Health. Drug Administration of Vietnam shall amend the list of facilities permitted to export, import addictive drugs, psychotropic medicines, and drug precursors for the purpose of supply to other facilities.

2. Any company that exports or imports addictive drugs, psychotropic drugs, or drug precursors must comply with:

a) Warehouse keepers must have bachelor’s degrees in pharmacy and worked for at least 02 years for drug sellers.

b) Any facility that exports or import addictive drugs, psychotropic drugs, and drug precursors must make and keep the following documents:

- A logbook of sales and purchases of addictive drugs, psychotropic drugs, drug precursors using the Template No. 2 enclosed herewith.

- Notes of delivery of addictive drugs, psychotropic drugs, drug precursors using the Template No. 3 enclosed herewith;

- Proof of export, import, sale, and purchase of addictive drugs, psychotropic drugs, or drug precursors.

3. Any company that exports or imports addictive drugs, psychotropic drugs, or drug precursors as prescribed in Clause 1 of this Article may:

a) Export, import addictive drugs, psychotropic drugs, and precursors;

b) Buying addictive drugs, psychotropic drugs, precursors, commercial combined drugs that contain addictive ingredients, combined drugs that contain psychotropic ingredients, or combined drugs that contain drug precursors from manufacturers;

c) Selling commercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs to the wholesalers mentioned in Clause 1 Article 6 of this Circular, the drugstores mentioned in Clause 1 Article 7 of this Circular, medical facilities, research institutes, laboratories, educational - labor - social institutes, opioid replacement therapy centers, healthcare - pharmacy training institutes nationwide.

d) Sell raw materials and semi-finished products that contain addictive ingredients, psychotropic ingredients, or drug precursors to facilities licensed to manufacture addictive drugs, psychotropic drugs, or drug precursors;

dd) Only directly import, not buy or sell addictive drugs, psychotropic drugs, or drug precursors of other drug exporters and drug importers. If drugs supply for patients is not sufficient, the exporter or import must notify Drug Administration of Vietnam.

4. Any facility that meets the conditions for selling drugs in Chapter II of the Law on Pharmacy, Chapter IV of the Government's Decree No. 79/2006/ND-CP, and the Decree No. 89/2012/ND-CP may export, import commercial combined drugs that contain addictive ingredients, combined drugs that contain psychotropic ingredients, or combined drugs that contain precursors; the following documents must be made and kept:

a) A log of export and import of commercial combined drugs that contain addictive ingredients, combined drugs that contain psychotropic ingredients, or combined drugs that contain drug precursors using Template No. 04 enclosed herewith;

b) Documents relevant to export, import, and trading of commercial combined drugs that contain addictive ingredients, combined drugs that contain psychotropic ingredients, or combined drugs that contain drug precursors;

5. A drug exporter or importer may only sell commercial combined drugs that contain addictive ingredients, combined drugs that contain psychotropic ingredients, or combined drugs that contain drug precursors to:

a) Medical facilities and drugstores that comply with GPP nationwide;

b) A drug wholesaler that has the certificate of eligibility for drug business in a province, who will then sell drugs to medical facilities and drugstores that comply with GPP within that province.

Article 6. Wholesaling

1. Any pharmaceutical company in a province that is supplying commercial addictive drugs , commercial psychotropic drugs, or commercial precursor drugs may keep buying such drugs from the companies mentioned in Clause 1 Article 5 of this Circular for the purpose of drug supply within that province.

If a pharmaceutical company in a province does not have sufficient drugs to supply local medical facilities, the Service of Health of that province shall send a report to Drug Administration of Vietnam, requesting appointment of a drug wholesaler who has as certificate of eligibility for

drug business to supply commercial addictive drugs , commercial psychotropic drugs, or commercial precursor drugs within the province.

2. Every of the company mentioned in Clause 1 of this Article must comply with the following regulations:

a) Warehouse keepers must have bachelor's degrees in pharmacy and worked for at least 02 years for drug sellers or drug manufacturers.

b) Records:

- A logbook of sales and purchases of addictive drugs, psychotropic drugs, drug precursors using the Template No. 2 enclosed herewith.

- Notes of delivery of addictive drugs, psychotropic drugs, drug precursors using the Template No. 3 enclosed herewith;

- Documents about the export, import, sale, and purchase of addictive drugs, psychotropic drugs, or drug precursors.

3. Any of the companies mentioned in Clause 1 of this Article may:

a) Buy commercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs from the drug exporters and importers mentioned in Clause 1 Article 5 of this Circular.

b) Sell comercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs to the drugstores that comply with GPP as prescribed in Clause 1 Article 7 of this Circular, medical facilities, research institutes, laboratories, training - labor - social centers, opioid replacement therapy centers, and healthcare - pharmacy training centers within the province.

4. Any facility that satisfy requirements for drug business in Chapter II of the Law on Pharmacy, Chapter IV of the Government's Decree No. 79/2006/ND-CP dated August 09, 2006, and the Government's Decree No. 89/2012/ND-CP dated August 09, 2006 may buy, sell commercial combined drugs that contain addictive ingredients, combined drugs that contain psychotropic ingredients, or combined drugs that contain drugs precursors, and must make and keep the following documents:

a) A log of sales and purchases of commercial combined drugs that contain addictive ingredients, combined drugs that contain psychotropic ingredients, or combined drugs that contain drug precursors using Template No. 04 enclosed herewith;

b) Documents relevant to trading of commercial combined drugs that contain addictive ingredients, combined drugs that contain psychotropic ingredients, or combined drugs that contain drug precursors;

5. Every wholesaler of commercial combined drugs that contain addictive ingredients, combined drugs that contain psychotropic ingredients, or combined drugs that contain drug precursors within the province must notify the Service of Health of the articles they sell and any change that is made, and may only supply drugs to medical facilities and drugstores that comply with GPP within that province.

Article 7. Retailing

1. Any drugstore that comply with GPP may retail commercial addictive drugs, commercial psychotropic drugs, commercial precursor drugs, commercial combined drugs that contain

addictive ingredients, combined drugs that contain psychotropic ingredients, or combined drugs that contain drug precursors to outpatients.

Every drugstore that sells commercial addictive drugs must apply for a registration with the Service of Health and adhere to regulations in this Circular.

2. Owners of drugstores and persons in charge of expertise are responsible for management and retailing of commercial addictive drugs.

3. Holders of associate degrees in pharmacy or higher may manage and retail commercial psychotropic drugs and precursor drugs.

4. Any of the drugstores mentioned in Clause 1 of this Article may buy commercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs; commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors from drugs exporters and importers defined in Clause 1 Article 5, and from drug wholesalers defined in Clause 1 Article 6 of this Article, and may retail drugs as prescribed.

Commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors on the list of OTC drugs promulgated by the Ministry of Health may be sold to patients without prescriptions. Information about customers must be recorded.

5. Drugstores must not buy, sell raw materials or semi-finished products that contain addictive ingredients, psychotropic ingredients, or drug precursors.

6. Drugstores that retail commercial addictive drugs, commercial psychotropic drugs, and commercial precursors drugs must record and keep the following documents:

a) A logbook of sales and purchases of addictive drugs, psychotropic drugs, drug precursors using the Template No. 2 enclosed herewith.

b) Notes of delivery of addictive drugs, psychotropic drugs, and precursors of the drug suppliers;

c) Prescriptions of addictive drugs keep by the seller after drugs are sold;

d) Notes of receipts of commercial addictive drugs submitted by patients' families.

dd) A logbook of customers using Template No. 07 enclosed herewith.

Chapter III

PRESCRIPTION, PREPARATION, DISPENSING, AND USE OF DRUGS

Article 8. Prescription

1. Prescription of commercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs for outpatients must comply with "Regulation on prescription of outpatient drugs" promulgated by the Minister of Health.

2. Prescription of commercial addictive drugs, commercial psychotropic drugs, and commerical precursor drugs for inpatients must comply with the Circular on guidelines for use of drugs in medical facilities having hospital beds promulgated by the Minister of Health.

3. Commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug

precursors on the list of OTC drugs promulgated by the Ministry of Health may be sold to patients without prescriptions.

4. Commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors that are not on the list of OTC drugs promulgated by the Ministry of Health may only be used when prescribed by qualified physicians. Drug sellers may only sell drugs to patients when having prescriptions given by qualified physicians.

Article 9. Drug preparation at hospitals

1. Any hospital that prepares commercial addictive drugs, commercial psychotropic drugs, commercial precursor drugs, commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors must have a preparation area that satisfy the following requirements:

a) Facilities:

- The preparation room must have a dust-resist ceiling; the floor and walls are made of materials that Article easy to clean and sterilize when necessary. The room must be built at a location that is airy, safe, isolated, and far away from polluting sources. The minimum area is 10 m^2. The units must be arranged in one way;

- There is an area for washing hands and preparation equipment;

- There are sufficient equipment for preparing, preserving, and testing drugs.

b) Personnel:

- The person in charge of recording, reporting, and inspecting quality of prepared drugs must have a bachelor's degree in pharmacy.

- The person in charge of management of prepared commercial addictive drugs must have a bachelor’s degree in pharmacy.

- The person in charge of commercial psychotropic drugs or commercial precursor drugs must have an associate degree in pharmacy or above.

c) Packaging, labeling, preservation:

- Commercial addictive drugs, commercial psychotropic drugs, and commercial precursors drugs must be packaged, labeled immediately after preparation to avoid confusion. The label must contain: name of the facility, name of the drug, dosage form, active ingredients, their concentration, preparers, supervisors, date of preparation, and date of expiry.

- Addictive drugs, psychotropic drugs, and drug precursors must be preserved in separate cabinets. Measures and equipment shall be employed to ensure safety and prevent leakage.

d) Records:

- Logbook of preparation of addictive drugs, psychotropic drugs, and precursors Template 1;

- Logbook of drug quality control;

- Process of preparing prescription drug;

- SOP for drug preparation.

2. Scope:

a) Prepared drugs may only be sold and dispensed by prescription to inpatients and outpatients of the facility;

b) Only drugs with formula, preparation process, and quality standards approved by the head of the facility may be prepared, who is responsible for the safety and effectiveness of such drugs;

c) Do not prepare injectable medicines.

Article 10. Preparation and use of drugs at research/training institutes for healthcare - pharmacy

1. Research/training institutes for healthcare - pharmacy may prepare, use addictive drugs, psychotropic drugs, precursors, commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors to serve the teaching and scientific research; pharmacy graduates shall supervise the preparation and keep a log of the preparation, sales, purchases of addictive drugs, psychotropic drugs, precursors, and submit reports in accordance with this Circular.

2. Commercial addictive drugs, commercial psychotropic drugs, and commercial precursors drugs must be packaged, labeled immediately after preparation in accordance with Point c Clause 1 Article 9 of this Circular.

Article 11. Dispensing and using

1. The pharmacy ward shall dispense drugs to treating wards according to the orders for commercial addictive drugs, commercial psychotropic drugs, and commerical precursor drugs (Template No. 8 enclosed herewith) directly dispense drugs to outpatients.

The head of the pharmacy ward or a pharmacy graduate authorized in writing by the head shall sign the orders for commercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs.

2. The head of each treating ward shall sign the order for commercial addictive drugs, commercial psychotropic drugs, and commerical precursor drugs used by his/her ward.

At treating wards, after receiving drugs from the pharmacy ward, the nurses in charge shall check, compare the names, concentrations, and quantity of drugs before injecting or dispensing to patients.

Commercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs that are unused must be returned to the pharmacy ward. Such return must be recorded in writing. The head of the pharmacy ward shall decide to keep them or destroy them, then make a record and keep it at the pharmacy ward;

The pharmacy ward must monitor and record the quantity of commercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs that are received, used, and unused using Template No. 02 enclosed herewith.

The keeper of the addictive drug warehouse must have a bachelor's degree or associate degree in pharmacy and be authorized in writing by the head of the facility (each authorization does not last for more than 12 months).

The keeper of the warehouse ofpsychotropic drugs and drug precursors must have at least an associate degree in pharmacy.

2. Treating wards of medical facilities: commercial addictive drugs, commercial psychotropic drugs, and commerical precursor drugs must be separated in the emergency medicine cabinets, kept and dispensed by the nurses working the shift When changing shifts, the nurses shall handover drugs and the logbook to the persons doing the next shift.

3. Training - labor - social centers, opioid replacement therapy centers: commercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs must be managed, dispensed, and monitored by holders of associate degrees or bachelor's degrees in pharmacy (authorized in writing by the head of the facility).

4. Commercial psychotropic drugs for community mental health programs at health stations of communes, wards and towns must be managed and dispensed by holders of associate degrees in pharmacy or healthcare or higher.

Chapter IV

DELIVERY, TRANSPORT, AND PRESERVATION OF DRUGS

Article 12. Delivery

1. When delivering addictive drugs, psychotropic drugs, precursors, commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors, the delivery man and the recipient must physically check the name, concentration, quantity, batch number, expiry date, and quantity of drugs; sign and write their full names on the delivery note.

2. The deliveryman and recipient of addictive drugs, psychotropic drugs, and drug precursors must have at least associate degrees in pharmacy.

Article 13. Transport

1. Addictive drugs, psychotropic drugs, precursors, commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors must be packaged, sealed, and protected during transport; the packages must specify the manufacturer, buyer, name and quantity of drugs.

2. The head of the facility must appoint (in writing) an employee who has an associate degree in pharmacy to take charge of the transport of addictive drugs, psychotropic drugs, and drug precursors; the person in charge of the transport must carry the letter of appointment, ID card (or another ID paper), sale invoice or delivery note; physically check the categories, quantity, and quality of drugs during the transport, and transfer them in full to the recipient.

3. In case a business establishment has to hire a deliverer to transport addictive drugs, psychotropic drugs, or drug precursors: the hirer and the deliver must conclude a contract specifying requirements in terms of preservation, transport, transfer of drugs as prescribed. The recipient must satisfy such requirements during the transport and ensure no loss of drugs.

The hirer and the deliverer are responsible for the issues related to addictive drugs, psychotropic drugs, or drug precursors during the transport.

The deliverer and recipient of addictive drugs, psychotropic drugs, and drug precursors must have at least associate degrees in pharmacy.

Article 14. Preservation

1. Every drug manufacturer must have a separate warehouse that comply with Good Storage Practice promulgated by the Minister of Health to preserve raw materials, commercial addictive drugs, commercial psychotropic drugs, commercial precursor drugs, commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, and commercial combined drugs procedures contain precursors. The warehouse must have doors with firmly locks to ensure safety and prevent loss.

2. Every drug exporter and importer mentioned in Clause 1 Article 5 of this Circular must have a separate warehouse that comply with "Good Storage Practice", has an area of at least 100 m^2 and a volume of at least 300 m^3, doors that are firmly locked.

3. Every drug wholesaler mentioned in Clause 1 Article 6 of this Circular must have firmly locked warehouses that comply with "Good Storage Practice", including one for preserving commercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs. If a separate warehouse is not available, the commercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs must be placed in a separate area in a warehouse that complies with Good storage practice.

4. Any exporter, importer, or wholesaler of commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors must have a warehouse that is firmly locked and comply with Good storage practice.

5. Each drugstore must have separate cabinets with firm locks to preserve commercial addictive drugs, commercial psychotropic drugs, and commerical precursor drugs.

If the quantity of commercial addictive drugs is small, they may be stored in the same cabinet with commercial psychotropic drugs and commercial precursor drugs, provided they are placed in separated compartments to avoid confusion; the cabinet must be firmly locked.

Commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, and commercial combined drugs that contain precursors must be placed in separated areas.

6. Emergency medicine cabinet:

Commercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs in the emergency medicine cabinet must be placed in separate compartments. The cabinets must be firmly locked. The quantity and categories of commercial addictive drugs, commercial psychotropic drugs, and commerical precursor drugs in the emergency medicine cabinet shall be decided in writing by the head of the facility.

7. Pharmacy ward: commercial addictive drugs, commercial psychotropic drugs, and commercial precursor drugs must be preserved in a warehouse that complies with "Good Storage Practice" promulgated by the Ministry of Health. Measures shall be taken to ensure safety and avoid loss.

The warehouse or cabinet where commercial addictive drugs, commercial psychotropic drugs, and commerical precursor drugs are stored must be firmly locked. If a separate warehouse or cabinet is not available, commercial addictive drugs may be stored together with commercial psychotropic drugs and commerical precursor drugs, provided they are separated from one another to avoid confusion.

Commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, and commercial combined drugs that contain precursors must be placed in separated areas.

8. Research institutes, training institutions and relevant units: addictive drugs, psychotropic drugs, and drug precursors must be stored in separate compartments in firmly locked cabinets. Measures and equipment shall be employed to ensure safety and preven leakage. Commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, and commercial combined drugs that contain precursors must be placed in separated areas.

9. Health stations of communes: commercial psychotropic drugs must be stored in firmly locked cabinets.

Chapter V

DOCUMENTATION, PROCEDURES FOR LICENSING, REPORTING, DRUG DESTRUCTION

Article 15. Estimation

1. Every drug wholesaler, drug retailer, and facility that use drugs must make an estimate of necessary purchase commercial addictive drugs, commercial psychotropic drugs, and commerical precursor drugs using Template No. 09 enclosed herewith.

2. Every manufacturer of commercial addictive drugs, commercial psychotropic drugs, commercial precursor drugs, commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, commercial combined drugs that contain drug precursors shall make purchase orders for raw materials and semi-finished products that contain addictive ingredients, psychotropic ingredients, and precursors using Template No. 10 enclosed herewith; or make purchase orders for raw materials and semi-finished products that contain psychotropic ingredients or drug precursors in accordance with the Circular on guidelines for export, import of drugs and immediate drug packages promulgated by the Ministry of Health.

3. Every drug exporter and importer shall make orders for export and import of addictive drugs, psychotropic drugs, drug precursors in accordance with the Circular on guidelines for export, import of drugs and immediate drug packages promulgated by the Ministry of Health.

4. The estimate shall be made into 04 copies (02 copies are kept by the approving authority, 01 copy is kept by the maker, and 01 copy is kept by the seller)

5. Every drug wholesaler, drug retailer, and facility that uses commercial addictive drugs , commercial psychotropic drugs, or commercial precursor drugs may only buy, sell, dispense and use such drugs after the estimate is approved.

6. The head of the company is responsible for the estimated quantity of commercial addictive drugs , commercial psychotropic drugs, or commercial precursor drugs. The estimate quantity must be appropriate for the demand of the facility. The estimate of addictive drugs, psychotropic drugs, and drug precursors may exceed the previous estimate by more than 50% in case of drug shortage, emergencies, natural disasters, or epidemics.

7. Companies that manufacture, export, import, wholesale, retail, facilities that use commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors are not required to make estimates as prescribed above.

8. The estimate shall be considered within 07 working days from the receipt of the valid estimate. If it is not approved of, a written explanation shall be provided.

Article 16. Approving estimates

1. Drug Administration of Vietnam - the Ministry of Health shall:

a) Consider approving estimates of addictive drugs, psychotropic drugs, drug precursors made by drug manufacturers, medical facilities, research institutes, laboratories, training institution for healthcare - pharmacy;

b) Consider approving orders for export and import of addictive drugs, psychotropic drugs, drug precursors made by drug exporters and drug importers prescribed in Clause 1 Article 5 of this Circular;

c) Consider approving estimates of addictive drugs, psychotropic drugs, drug precursors made by facilities other than those under the management of health authorities and need to buy addictive drugs for the purpose of scientific research according to scientific research outlines approved by competent authorities;

d) Consider approving estimates of commercial addictive drugs, commercial psychotropic drugs, and commerical precursor drugs made by Army Medical Department - the Ministry of National Defense.

2. Provincial Services of Health shall consider approving estimates of commercial addictive drugs, commercial psychotropic drugs, and commerical precursor drugs made by drug wholesalers, drug retailers, medical facilities (except for units affiliated to the Ministry of National Defense and the Ministry of Transport), research institutes and training institutes for healthcare - pharmacy. In each province, the Service of Health may delegate Health Divisions or medical centers of districts to consider approving estimates of commercial addictive drugs, commercial psychotropic drugs, and commerical precursor drugs made by health stations of communes.

3. Army Medical Department - Ministry of National Defense shall consider approving estimates of commercial addictive drugs, commercial psychotropic drugs, and commerical precursor drugs made by hospitals and units affiliated to the Ministry of National Defense.

4. Medical Department - Ministry of Transport shall consider approving estimates of commercial addictive drugs, commercial psychotropic drugs, and commerical precursor drugs made by hospitals and units affiliated to the Ministry of Transport.

Article 17. Necessary documentation and procedures for licensing export and import

1. Necessary documentation and procedures for export, import of addictive drugs, psychotropic drugs, drug precursors, commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, commercial combined drugs that contain drug precursors shall comply with the Circular on guidelines for export, import of drugs and immediate drug packages promulgated by the Ministry of Health.

2. The license for export/import of addictive drugs is yellow, for psychotropic drugs is blue, and for drug precursors is pink, which is issued to each export/import, and valid for up to 01 year from the day on which it is signed.

3. The license for export/import of addictive drugs, psychotropic drugs, and drug precursors shall be sent to the applicant, the Drug Prevention Department - Ministry of Public Security, Sub-department of Customs at the border checkpoint where export/import procedures are followed; the Ministry of Finance (Smuggling Investigation and Prevention Department - The General Department of Customs); International Narcotics Control Board; and the authority of the importing country (applied to export licenses).

4. Addictive drugs, psychotropic drugs, drug precursors may only be exported or imported through border checkpoints of Vietnam.

Article 18. Retention of records

1. Any manufacturer, exporter, wholesaler, retailer of addictive drugs, psychotropic drugs, or drug precursors; any establishment that uses, prepare, dispense addictive drugs, psychotropic drugs, or drug precursors; and establishment that provide services related to addictive drugs, psychotropic drugs, or drug precursors must retain records on such drugs for at least 02 years after expiry dates of drugs. Prescription N shall be kept in accordance with “Regulation on outpatient prescription” promulgated by the Minister of Health.

2. Any establishment that manufactures commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, commercial combined drugs that contain drug precursors shall retain records on the raw materials and semi-finished products that contain addictive ingredients, psychotropic ingredients or drug precursors for at least 02 years after expiry dates of drugs

3. After the said period, the head of the establishment shall establish a council to carry out drug destruction, make a record, and keep the record at the establishment.

Article 19. Reporting

1. Export, import reports:

a) Addictive drugs, psychotropic drugs, drug precursors: within 10 days after export or import, the exporter or importer shall submit a report using Template No. 11A or 11B enclosed herewith to Drug Administration of Vietnam - Ministry of Health and Department of Drug and Crime Prevention - Ministry of Public Security;

b) Every year, every drug exporter and importer shall submit a report on the quantity of exported/imported commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, commercial combined drugs that contain drug precursors using Template No. 12A or 12B enclosed herewith to Drug Administration of Vietnam by January 15 of the next year.

2. Report on used and unused drugs:

a) Every exporter, importer, wholesaler, retailer of addictive drugs, psychotropic drugs, drug precursors, every establishment that uses addictive drugs, psychotropic drugs, drug precursors shall biannually submit reports on used and unused drugs by July 15, and January 15 using Template 13A and 13B enclosed herewith to the authority that considers approving the estimate (hereinafter referred to as approving authority);

b) Every exporter, importer, wholesaler, and retailer of commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors shall biannually submit reports sold/unsold drugs and addresses of customers by July 15, and January 15 to the Service of Health of the province.

c) Every manufacturer and importer of commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, or commercial combined drugs that contain drug precursors shall send Drug Administration of Vietnam a report on the quantity of purchased, imported, unsold, and sold quantity, names and addresses of customers every time the request for permission to buy/import raw materials for drug manufacture is made and every year by January 15 of the next year; the Service of Health must be notified of the articles sold by local companies.

d) Services of Health shall report the use of addictive drugs, psychotropic drugs, and drug precursors by local establishments using Template No. 14 enclosed herewith;

dd) Army Medical Department - Ministry of National Defense shall send a report on use of addictive drugs, psychotropic drugs, and drug precursors by the military using Template No. 11A enclosed herewith to Drug Administration of Vietnam by January 30 of the next year.

3. Report on confusion, loss, or suspected loss:

In case of confusion, loss, or suspected loss, the entity having activities related to addictive drugs, psychotropic drugs, drug precursors, commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, commercial combined drugs that contain drug precursors must send an urgent report to the approving authority. When receiving the urgent report, the approving authority shall carry out verification and take appropriate measures;

Services of Health shall submit a summary report on urgent reports to Drug Administration of Vietnam.

Article 20 . Drug destruction

1. Raw materials, semi-finished products that contain addictive ingredients, psychotropic ingredients, or drug precursors; commercial addictive drugs, commercial psychotropic drugs, commerical precursor drugs, that are expired, substandard, drug samples after retention period, and drugs returned from treating wards must be destroyed as follows:

a) Submit a written request for permission for drug destruction to the approving authority. The written request for permission for drug destruction must specify the names, concentration of drugs, reasons for destruction, and destruction method. Drug destruction may only be carried out after it is approved by the approving authority;

b) Establish a drug destruction council decided by the head of the facility. The council is composed of at least 03 people, including an executive officer of the facility;

c) Make a drug destruction record and keep it at the facility;

d) Send a report on drug destruction to the approving authority (enclosed with the drug destruction record).

2. Residual products and waste during the manufacture of addictive drugs, psychotropic drugs, drug precursors, commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, commercial combined drugs that contain drug precursors must be collected and destroyed in accordance with Point b and Point c Clause 1 of this Article.

3. Drug manufacturers and drug sellers must collect and destroy immediate packages of addictive drugs, psychotropic drugs, drug precursors in accordance with Point b and Point c Clause 1 of this Article.

Facilities that use addictive drugs, psychotropic drugs, drug precursors must collect and destroy immediate packages of them (including bottles, jars, tubes) in accordance with Point b and Point c Clause 1 of this Article.

4. The destruction of addictive drugs, psychotropic drugs, drug precursors, commercial combined drugs that contain addictive ingredients, commercial combined drugs that contain psychotropic ingredients, commercial combined drugs that contain drug precursors must be separate from destruction of other kinds of drugs, ensure absolute safety of humans, animals, avoid environmental pollution in accordance with regulations of law on environment protection.

Chapter VI

IMPLEMENTATION

Article 21. Implementation

1. This Circular takes effect on July 15, 2014.

2. The Circular No. 10/2010/TT-BYT dated April 29, 2010 of the Minister of Health on guidelines for activities related to addictive drugs, the Circular No. 11/2010/TT-BYT dated April 29, 2010 of the Minister of Health on guidelines for activities related to psychotropic drugs and drug precursors are annulled from the effective date of this Circular.

Difficulties that arise during the implementation of this Circular should be reported to the Ministry of Health (Drug Administration of Vietnam) for consideration./.

MINISTER

Nguyen Thi Kim Tien

APPENDIX I

ADDICTIVE INGREDIENTS

No.	INTERNATIONAL NAME	SCIENTIFIC NAME
1.	ACETYLDIHYDROCODEIN	(5 a, 6 a)- 4,5- epoxy-3- methoxy-17 methyl-morphinan-6-yl-acetat
2.	ALFENTANIL	N-[1-[2-(4-ethyl-4,5- dihydro-5-oxo-1 H-tetrazol-1-yl) ethyl]-4- (methoxymethyl)-4-piperidinyl]- N- Phenylpropanamide
3.	ALPHAPRODINE	a- 1,3- dimethyl-4- phenyl-4-propionoxypiperidine
4.	ANILERIDINE	1- para-aminophenethyl-4- phenylpiperidine-4-carboxylic acid ethyl ester)
5.	BEZITRAMIDE	(1-(3- cyano- 3,3- diphenylpropyl)- 4 (2- oxo-3- propionyl-1- benzimidazolinyl)- piperidine)
6.	BUTORPHANOL	(-)- 17- (cyclobutylmethyl) morphinan- 3,14 diol
7.	CIRAMADOL	(-)-2- (a- Dimethylamino-3- hydroxybenzyl) Cyclohexanol
8.	COCAINE	Methyl ester of benzoylecgonine
9.	CODEINE	(3- methylmorphine)
10.	DEXTROMORAMIDE	((+)-4 [2- methyl-4- oxo-3,3- diphnyl-4 (1-pyrrolidinyl)- butyl]- morpholine)
11.	DEZOCIN	(-)- 13 b- Amino- 5,6,7,8,9,10,11 a, 12 octahydro- 5a- methyl-5, 11- methanobenzo-cyclodecen-3- ol
12.	DIFENOXIN	(1- (3 cyano- 3,3- Diphenylpropyl)- 4-Phenylisonipecotic acid
13.	DIHYDROCODEIN	6- hydroxy- 3- methoxy-N- methyl-4,5- epoxy-morphinan
14.	DIPHENOXYLATE	1-(3-cyano-3,3-diphenylpropyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester
15.	DIPIPANONE	4,4- Diphenyl-6- Piperidino-3- heptanone.
16.	DROTEBANOL	(3,4- Dimethoxy- 17- Methyl morphinan-6 b, 14 diol)
17.	ETHYL MORPHIN	3- Ethylmorphine
18.	FENTANYL	(1- Phenethyl-4-N-Propionylanilinopiperidine)
19.	HYDROMORPHONE	(Dihydromorphinone)
20.	KETOBEMIDON	(4- meta- hydroxyphenyl-1- methyl-4-propionylpiperidine)
21.	LEVOMETHADON	(3- Heptanone, 6- (dimethylamino)-4,4-Diphenyl, (R)
22.	LEVORPHANOL	((-)- 3- hydroxy- N- methylmorphinan)
23.	MEPTAZINOL	(3(3- Ethyl-1- methylperhydroazepin-3- yl) phenol
24.	METHADONE	(6- dimethylamino- 4,4- diphenyl-3-heptanone)

25.	MORPHINE	Morphinan-3,6 diol, 7,8-didehydro- 4,5-epoxy-17 methyl - (5 a, 6 a)
26.	MYROPHINE	MyristylBenzylmorphine
27.	NALBUPHIN	17- Cyclobutylmethyl- 7,8- dihydro- 14-hydroxy- 17- normorphine
28.	NICOCODINE	Morphinan- 6- ol, 7,8- Dihydrro- 4,5- epoxy- 3- methoxy- 17- methyl- 3- pyridin mecarboxxylate (ester), (5a, 6a)
29.	NICODICODINE	6- Nicotinyldihydrocodeine
30.	NICOMORPHINE	3,6- Dinicotinylmorphine)
31.	NORCODEINE	N- Dimethylcodein
32.	OXYCODONE	(14- hydroxydihydrocodeinone)
33.	OXYMORPHONE	(14- hydroxydihydromorphinone)
34.	PETHIDINE	(1- methyl-4- phenylpiperidine-4- carboxylic acid ethyl ester)
35.	PHENAZOCINE	(2'- Hydroxy-5,9- Dimethyl-2- Phenethyl-6,7-Benzomorphan)
36.	PHOLCODIN	(Morpholinylethylmorphine)
37.	PIRITRAMIDE	(1-(3- cyano-3,3- diphenylpropyl-4-(1-piperidino)- piperidine- 4- carboxylic acid amide)
38.	PROPIRAM	(N- (1- Methyl- 2 piperidinoethyl- N- 2-pyridyl Propionamide)
39.	REMIFENTANIL	1-(2-methoxy carbonylethyl)-4-(phenylpropionylamino)piperidine-4-carboxylic acid methyl ester
40.	SUFENTANIL	(N-[4- (methoxymethyl)-1- [2- (2- thienyl)-ethyl]-4- piperidyl]- propionanilide)
41.	THEBACON	(Acetyldihydrocodeinone)
42.	TONAZOCIN MESYLAT	(+)-1- [(2R*,6S*,11S*)- 1,2,3,4,5,6-hexahydro- 8- hydroxy- 3,6,11- trimethyl- 2,6-methano-3- Benzazocin- 11- yl]-3-one-methanesulphonate
43.	TRAMADOL	(+)- Trans- 2- Dimethylaminomethyl-1-(3-methoxy phenyl) cyclohexan-1-ol

* This Table includes:

- Esters and ethers of substances in the Table if they are not enumerated in other Tables, provided such esters and ethers exist.

- Salts of substances in this Table, including salts of esters, ethers, and isomers thereof, provided such salts exist.

APPENDIX II

LIMITS ON ADDICTIVE INGREDIENTS IN COMMERCIAL COMBINED DRUGS

No.	NAME OF ADDICTIVE INGREDIENT	CONCENTRATION IN THE FORM OF ALKALI IN A DIVIDED DOSE (Expressed as mg)	CONCENTRATION IN THE FORM OF ALKALI IN A SINGLE-DOSE PRODUCTS (Expressed as %)
1.	ACETYLDIHYDROCODEIN	100	2.5
2.	COCAINE		0.1
3.	CODEINE	100	2.5
4.	DIFENOXIN	Not exceeding 0.5 mg of Difenoxin and with at least 0.025 mg of Atropin Sulfate in a divided dose	
5.	DIPHENOXYLATE	Not exceeding 2.5 mg of Difenoxylat and with at least 0.025 mg of Atropin Sulfate in a divided dose	
6.	DIHYDROCODEIN	100	2.5
7.	ETHYL MORPHIN	100	2.5
8.	NICODICODIN	100	2.5
9.	NORCODEIN	100	2.5
10.	PHOLCODIN	100	2.5
11.	PROPIRAM	100	2.5
12.	MORPHINE		0.2 morphine expressed as pure morphine base
13.	TRAMADOL	37.5	

APPENDIX III

PSYCHOTROPIC INGREDIENTS

No.	INTERNATIONAL NAME	OTHER COMMON NAME	SCIENTIFIC NAME
1.	ALLOBARBITAL		5,5-diallylbarbituric acid
2.	ALPRAZOLAM		8- chloro -1- methy -6- phenyl – 4H -s- triazolo [4,3-a] [1,4] benzodiazepine
3.	AMFEPRAMONE	Diethylpropion	2-(diethylamino) propiophenone

4.	AMINOREX		2- amino-5- phenyl- 2-oxazoline
5.	AMOBARBITAL		5-ethyl-5-isopentylbarbituric acid
6.	BARBITAL		5,5-diethylbarbituric acid
7.	BENZFETAMINE	Benzphetamine	N-benzyl-N, a-dimethylphenethylamine
8.	BROMAZEPAM		7-bromo-1,3-dihydro-5-(2-pyridyl)-2H-1,4-benzodiazepin-2-one
9.	BROTIZOLAM		2- bromo-4-(o-chlorophenyl)-9 methyl-6H-thieno(3,2-f)-s-triazolo(4,3- a)(1,4) diazepine
10.	BUPRENORPHINE		21-cyclopropyl-7-a[(S)-1-hydroxy-1,2,2-trimethylpropyl]-6,14-endo-ethano-6,7,8,14-tetrahydro oripavine
11.	BUTALBITAL		5-allyl-5-isobutylbarbituric acid
12.	BUTOBARBITAL		5-butyl-5- ethylbarbituric acid
13.	CAMAZEPAM		7-chloro-1,3-dihydro-3-hydroxy-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one dimethylcarbamate (ester)
14.	CHLODIAZEPOXID		7-chloro-2-(methylamino)-5-phenyl-3H-1,4-benzodiazepine-4-oxide
15.	CATHINE	(+)-norpseudo-ephedrine	(+)-(*R*)-a-[(R)-1-aminoethyl]benzyl alcohol
16.	CLOBAZAM		7-chloro-1-methyl-5-phenyl-1H-1,5-benzodiazepin-2,4 (3H,5H) dione
17.	CLONAZEPAM		5- (o-chlorophenyl)-1,3-dihydro-7- nitro- 2H -1,4 -benzodiazepine-2 –one
18.	CLORAZEPATE		7- chloro - 2,3 - dihydro - 2 - oxo -5-phenyl-1H-1,4-benzodiazepine -3-carbocilic acid
19.	CLOTIAZEPAM		5-(o-chlorophenyl)-7-ethyl-1,3 dihydro-1 methyl-2H-thieno[2,3e]-1,4 -diazepin -2-one
20.	CLOXAZOLAM		10-chloro-11b-(o-

			chlorophenyl)2,3,7,11b-tetrahydrooxazolo-[3,2-d] [1,4]benzodiazepin-6(5H) – one
21.	DELORAZEPAM		7-chloro-5- (o-chlorophenyl)-1,3 dihydro-2H-1,4 benzodiazepin-2 – one
22.	DIAZEPAM		7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4 benzodiazepin-2 – one
23.	ESTAZOLAM		8-chloro-6-phenyl-4H-s-triazolo[4,3-a][1,4]benzodiazepin
24.	ETHCHLORVYNOL		1 - chloro -3- ethyl -1- penten - 4 - yn -3-ol
25.	ETHINAMATE		1- ethynylcyclohexanol carbamate
26.	ETHYLLOFLAZEPATE		ethyl -7- chloro -5- (0-fluorophenyl) -2,3 - dihydro -2 - oxo -1H-1,4 -benzodiazepine -3- carboxylate
27.	ETILAMFETAMINE	N-ethylamphetamine	N-ethyl-a-methylphenethylamine
28.	FENCAMFAMIN		N- ethyl-3- phenyl-2-norbornanamine
29.	FENPROPOREX		(+) –3- [(a- methylphenethyl) amino] propionitrile
30.	FLUDIAZEPAM		7-chloro -5- (o-fluorophenyl) - 1,3-dihydro -1- methyl- 2H - 1,4- benzodiazepin -2- one
31.	FLUNITRAZEPAM		5-(o-fluorophenyl) -1,3 - dihydro-1- methyl -7- nitro-2H-1,4 benzodiazepin -2- one
32.	FLURAZEPAM		7-chloro-1-[2-(diethylamino)ethyl] -5-(o-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin -2 – one
33.	GLUTETHIMID		2-ethyl-2-phenylglutarimide
34.	HALAZEPAM		7-chloro-1,3- dihydro -5-phenyl-1-(2,2,2 - trifluoroethyl)-2H-1,4-benzodiazepin -2 – one
35.	HALOXAZOLAM		10-bromo-11b -(o-fluorophenyl)- 2,3,7,11b tetrahydrooxazolo [3,2-d] [1,4]

			benzodiazepin -6 (5H) –one
36.	KETAZOLAM		11-chloro -8,12b - (dihydro - 2,8 - dimethyl - 12b - phenyl - 4H -[1,3] oxazino[3,2-d][1,4] benzodiazepin-4,7 (6H)-dione
37.	KETAMIN		(+) –2- (2-Clorophenyl)-2-methylaminocyclohexanone.
38.	LEFETAMIN	SPA	(-)-N,N-dimethyl-1,2-diphenylethylamine
39.	LOPRAZOLAM		6-(o-chlorophenyl)-2,4-dihydro-2-[(4-methyl-1-piperazinyl) methylene] -8-nitro-1H-imidazol[1,2-a] [1,4] benzodiazepin -1 –one
40.	LORAZEPAM		7-chloro-5-(o-chlorophenyl)-1,3-dihydro-3-hydroxy-2H-1,4 benzodiazepin -2 – one
41.	LORMETAZEPAM		7-chloro-5-(o-chlorophenyl)-1,3-dihydro-3-hydroxy-1-methyl-2H-1,4 benzodiazepin -2 – one
42.	MAZINDOL		5-(p-chlorophenyl)- 2,5-dihydro -3H-imidazo[2,1-a] isoindol-5-ol
43.	MEDAZEPAM		7-chloro-2,3-dihydro-1-methyl-5-phenyl-1H-1,4 benzodiazepine
44.	MEFENOREX		N-(3- chloropropyl)- a -methylphenethylamine
45.	MEPROBAMAT		2-methyl-2-propyl - 1,3-propanediol, dicarbamate
46.	MESOCARB		3- (a methylphenethyl)- N-(phenylcarbamoyl) sydnone imine
47.	METHYLPHENIDATE		Methyl a -phenyl-2-piperidineacetate
48.	METHYLPHENO-BARBITAL		5-ethyl-1-methyl -5-phenylbarbituric acid
49.	METHYPRYLON		3,3 diethyl-5- methyl-2,4 piperydine- dione
50.	MIDAZOLAM		8- chloro- -6- (o-fluorophenyl) -1-methyl-4H-imidazol[1,5-a][1,4] benzodiazepine
51.	NIMETAZEPAM		1,3 dihydro -1- methyl-7-nitro-5-phenyl-2H-1,4

			benzodiazepin-2-one
52.	NITRAZEPAM		1,3 dihydro -7-nitro-5-phenyl-2H-1,4 benzodiazepin-2-one
53.	NORDAZEPAM		7-chloro- 1,3 dihydro-5-phenyl-2H-1,4 benzodiazepin-2-one
54.	OXAZEPAM		7-chloro- 1,3 dihydro-3hydroxy-5- phenyl-2H-1,4 benzodiazepin-2-one
55.	OXAZOLAM		10-chloro--2,3,7,11b-tetrahydro-2-methyl-11b-phenyloxazolo[3,2-d] [1,4] benzodiazepin-6(5H) –one
56.	PENTAZOCIN		(2R*,6R*,11R*)-1,2,3,4,5,6-hexahydro-6,11-dimethyl-3-(3-methyl-2-butenyl)-2,6-methano-3-benzazocin-8-ol
57.	PENTOBARBITAL		5-ethyl-5-(1-methylbutyl) barbituric acid
58.	PHENDIMETRAZIN		(+)-(2S,3S)-3,4-dimethyl-2-phenylmorpholine
59.	PHENOBARBITAL		5-ethyl-5-phenylbarbituric acid
60.	PHENTERMIN		a,a- dimethylphenethylamine
61.	PINAZEPAM		7-chloro-1,3-dihydro-5-phenyl-1-(2-propynyl)-2H-1,4-benzodiazepin-2-one
62.	PRAZEPAM		7-chloro -1- (cyclopylmethyl) -1,3 - dihydro -5- phenyl -2H-1,4-benzodiazepin-2-one
63.	PYROVALERONE		4’-methyl-2-(1-pyrrolidinyl) valerophenone
64.	SECBUTABARBITAL		5-sec-butyl-5-ethylbarbituric acid
65.	TEMAZEPAM		7- chloro - 1,3 - dihydro -3-hydroxy-1 -methyl-5-phenyl -2H- 1,4-benzodiazepin -2- one
66.	TETRAZEPAM		7-chloro-5-(1-cyclohexen-1-yl)-1,3dihydro-1-methyl-2H-1,4 benzodiazepin -2- one
67.	TRIAZOLAM		8-chloro-6-(o-chlorophenyl)-1-methyl-4H-s-triazolo[4,3-a][1,4] benzodiazepin
68.	VINYLBITAL		5-(1-methylbutyl)-5-vinylbarbituric acid
69.	ZOLPIDEM		N,N,6- trimethyl-2-p-

			tolylimidazol [1,2-a] pyridine-3- acetamide

* This Table includes salts of substances therein, provided such salts exist.

APPENDIX IV

LIMITS ON PSYCHOTROPIC INGREDIENTS IN COMMERCIAL COMBINED DRUGS

No.	NAME OF PSYCHOTROPIC INGREDIENT AND PRECURSOR	MAXIMUM CONCENTRATION IN A DIVIDED DOSE
1.	ALLOBARBITAL	10mg
2.	ALPRAZOLAM	0.25mg
3.	AMOBARBITAL	10mg
4.	BARBITAL	10mg
5.	BROMAZEPAM	1mg
6.	BROTIZOLAM	0.25mg
7.	BUTOBARBITAL	10mg
8.	CAMAZEPAM	5mg
9.	CHLODIAZEPOXID	5mg
10.	CLOBAZAM	5mg
11.	CLONAZEPAM	0.5mg
12.	CLORAZEPAT	10 mg
13.	CLOTIAZEPAM	5mg
14.	DIAZEPAM	5mg
15.	ESTAZOLAM	0.5mg
16.	FLUDIAZEPAM	0.5mg
17.	FLUNITRAZEPAM	0.5mg
18.	FLURAZEPAM	5mg
19.	HALAZEPAM	5mg
20.	KETAZOLAM	5mg
21.	LOPRAZOLAM	0.25mg
22.	LORAZEPAM	0.5mg
23.	LORMETAZEPAM	0.25mg
24.	MEPROBAMAT	100mg
25.	MEDAZEPAM	5mg
26.	METHYLPHENOBARBITAL	10mg
27.	MIDAZOLAM	5mg
28.	NITRAZEPAM	5mg
29.	NORDRAZEPAM	0.25mg
30.	OXAZEPAM	10mg
31.	PARAZEPAM	5mg
32.	PENTOBARBITAL	10mg

33.	PHENOBARBITAL	25 mg
34.	SECBUTABARBITAL	10mg
35.	TEMAZEPAM	25mg
36.	TETRAZEPAM	5mg
37.	VINYLBITAL	10mg
38.	CLOXAZOLAM	1mg
39.	DELORAZEPAM	0.25mg
40.	ETHYLCLOFLAZEPAT	0.25mg
41.	NIMETAZEPAM	0.25mg
42.	OXAZOLAM	5mg
43.	PINAZEPAM	1mg

APPENDIX V

DRUG PRECURSORS

No.	INTERNATIONAL NAME	SCIENTIFIC NAME
1.	EPHEDRINE	([R-(R*, S*)]--[1-(methylamino)ethyl]-Benzenemethanol
2.	N-ETHYLEPHEDRIN	1-Ethylephedrin
3.	N-METHYLEPHEDRIN/ METHYLEPHEDRIN/ DL-METHYLEPHEDRIN	(1R, 2S)-2- (dimethylamino)-1- phenyl-propanol
4.	PSEUDOEPHEDRINE	[S-(R*, R*)]--[1-(methylamino)ethyl]-Benzenemethanol
5.	ERGOMETRINE	Ergoline-8-carboxamide,9,10-didehydro-N-(2-hydroxy-1-methylethyl)-6-methy-[8 b(s)].
6.	ERGOTAMINE	Ergotaman-3',6',18'-trione,12'-hydroxy-2'-methyl-5'-(phenylmethyl)-(5)
7.	N-ETHYLPSEUDOEPHEDRIN	Ethyl methyl amino – phenyl – propane - 1 - ol
8.	N-METHYLPSEUDOEPHEDRIN	Dimethylamino – phenyl – propane – 1 - ol

* This Table includes salts of substances therein, provided such salts exist.

APPENDIX VI

LIMITS ON PRECURSORS IN COMMERCIAL COMBINED DRUGS

No.	PRECURSOR NAME	MAXIMUM CONCENTRATION IN A DIVIDED	MAXIMUM CONCENTRATION IN A SINGLE

		DOSE	DOSE
1.	EPHEDRINE	50 mg	1.5%
2.	ERGOMETRINE	0.125 mg	
3.	N- ETHYLEPHEDRIN	12.5 mg	
4.	N- METHYLEPHEDRIN	31.1 mg	
5.	ERGOTAMINE	01 mg	
6.	PSEUDOEPHEDRINE	120 mg	0.5%

APPENDIX VII

LIST OF EXPORTERS, IMPORTERS, AND SUPPLIERS OF ADDICTIVE DRUGS, PSYCHOTROPIC DRUGS, AND DRUG PRECURSORS

No.	COMPANY'S NAME
1.	Central Pharmaceutical Company No. 1
2.	Central Pharmaceutical Company No. 2
3.	Central Pharmaceutical Company No. 3
4.	Sapharco
5.	YTECO