

THE MINISTRY OF HEALTH

**CIRCULAR No. 06/2006/TT-BYT OF MAY 16, 2006, GUIDING THE IMPORT AND EXPORT OF
DRUGS AND COSMETICS**

Pursuant to Pharmacy Law No. 34/2005/QH11 of June 14, 2005;

Pursuant to Narcotics Prevention and Combat Law No. 23/2000/QH10 of December 9, 2000;

Pursuant to the Government's Decree No. 58/2003/ND-CP of May 29, 2003, providing for the control of import, export and transit through the Vietnamese territory of narcotics, pre-substances, habit-forming drugs and psychotropics;

Pursuant to the Government's Decree No. 12/2006/ND-CP of January 23, 2006, detailing the implementation of the Commercial Law regarding international goods sale and purchase and goods sale, purchase, processing and transit agency activities with foreign countries;

Pursuant to the Government's Decree No. 49/2003/ND-CP of May 15, 2003, defining the functions, tasks, powers and organizational structure of the Health Ministry;

The Health Ministry hereby guides the import and export of drugs and cosmetics as follows:

I. GENERAL PROVISIONS

1. Scope of regulation

1.1. This Circular governs activities of importing and exporting preventive and curative drugs for human use (called drugs for short), including finished drugs, raw materials for drug manufacture (pharmaceutical ingredients, materia medica, adjuvant, capsules and packings in direct contact with drugs) and cosmetics directly affecting human health, which are on the lists of those managed by the Health Ministry (called cosmetics for short).

1.2. The import of finished drugs without registration numbers or of raw materials for drug manufacture newly used in Vietnam (except habit-forming drugs, psychotropics and pre-substances used as drugs) shall be subject to separate guidance by the Health Ministry.

1.3. Drugs provided as humanitarian aids; drugs and cosmetics temporarily imported for re-export, temporarily exported for re-import or transferred from border-gate to border-gate; drugs imported or exported non-commercially, and vaccines, shall not be governed by this Circular.

2. Subjects of application

This Circular applies to Vietnamese traders, organizations and individuals involved in the import and export of drugs and cosmetics.

3. Rights to commercial import and export of drugs and cosmetics

3.1. For traders being Vietnamese enterprises which have no foreign direct investment capital:

a/ Enterprises having certificates of full eligibility for drug trading and drugstores up to Good Storing Practice (GSP) standards may directly import or be entrusted to import drugs.

b/ Enterprises which have been directly importing drugs before the effective date of this Circular but have neither certificates of full eligibility for drug trading nor drugstores up to GSP standards may continue importing drugs directly but shall have to urgently fill in the procedures to be granted certificates of full eligibility for drug trading by the Health Ministry and apply GSP principles under

the Health Minister's Decision No. 19/2005/QĐ-BYT of July 5, 2005, adjusting the plan on application of Good Manufacturing Practice (GMP) principles and standards, which were promulgated together with the Health Minister's Decision No. 3886/2004/QĐ-BYT of November 3, 2004, on the application of GMP principles and standards, as recommended by the World Health Organization (WHO) and GSP ones, promulgated together with the Health Minister's Decision No. 2701/2001/QĐ-BYT of June 29, 2001, on the application of GSP principles.

c/ Drug-manufacturing enterprises having GMP satisfaction certificates may import raw materials for drug manufacture.

3.2. For traders being foreign-invested enterprises in Vietnam:

a/ Foreign-invested drug manufacturing enterprises that have certificates of full eligibility for drug trading may directly import or be entrusted to import raw materials for manufacture of drugs in strict compliance with their investment licenses.

b/ Foreign-invested enterprises (other than those defined at Item a, Point 3.2 above) must not directly import and distribute drugs in Vietnam and may only do so via Vietnamese enterprises having drug import, export and distribution functions (except otherwise provided for by Vietnamese law).

3.3. Traders may export or entrust the export of drugs (except for habit-forming drugs, psychotropics and pre-substances used as drugs for export, which require export permits issued by the Health Ministry).

3.4. Traders may entrust the import of drugs (except for drugs on the list of those banned from import) within the scope provided for in their certificates of full eligibility for drug trading.

3.5. Traders may import and export cosmetics regardless of their registered business lines.

3.6. Organizations and individuals other than traders shall, on the basis of contracts signed according to law, be entrusted to import or export drugs to meet their own use demands (except for drugs on the list of those banned from import or suspended from export).

3.7. For foreign companies supplying import drugs for Vietnam

a/ Foreign companies having operation licenses for drugs and raw materials for drug manufacture in Vietnam may, within the scope of their operation specified in the licenses, supply finished drugs and raw materials for drug manufacture to Vietnamese drug-importing enterprises.

Where rare drugs are needed to meet medical treatment demands or raw materials are required for drug manufacture but cannot be supplied by the licensed companies, the Health Ministry shall consider to permit the import of such drugs from prestigious companies in the world.

With regard to materia medica, adjuvant, capsules and packings in direct contact with imported drugs, foreign suppliers need not have operation licenses for drugs and raw materials for drug manufacture in Vietnam.

b/ Foreign companies having operation licenses for drugs and raw materials for drug manufacture in Vietnam may supply finished drugs and raw materials bearing manufacturers' registration numbers to registering Vietnamese enterprises or to importing enterprises which are fully eligible for directly importing such drugs or raw materials under the provisions of this Circular.

4. General conditions on import and export of drugs and cosmetics

4.1. The import and export of habit-forming drugs, psychotropics and pre-substances for use as drugs must comply with the following regulations:

a/ The Regulation on management of habit-forming drugs, issued together with the Health Minister's Decision No. 2033/1999/QĐ-BYT of July 9, 1999, and Decision No. 1442/2002/QĐ-BYT of April 25, 2002, amending a number of articles of this Regulation.

b/ The Regulation on management of psychotropics, issued together with the Health Minister's Decision No. 3047/2001/QĐ-BYT of July 12, 2001, and Decision No. 1443/2002/QĐ-BYT of April 25, 2002, amending and supplementing a number of articles of this Regulation; and Decision No. 71/2004/QĐ-BYT of January 9, 2004, adding a number of substances to the List of psychotropics and pre-substances in the Regulation on management of psychotropics, issued together with the Health Minister's Decision No. 3047/2001/QĐ-BYT of July 12, 2001.

c/ The provisions of this Circular and other relevant provisions of law.

4.2. Quality of imported drugs and cosmetics

Traders producing, importing or exporting drugs and/or cosmetics; traders entrusting or being entrusted to import or export drugs and/or cosmetics shall be responsible for the quality of imported or exported drugs and cosmetics according to the provisions of the Pharmacy Law, the Commercial Law and the Regulation on management of the quality of drugs, issued together with the Health Minister's Decision No. 2412/1998/QĐ-BYT of September 15, 1998, and relevant provisions of law.

4.3. Use duration of drugs

a/ Finished drugs imported into Vietnam must have a remaining use duration of at least 18 months, counting from the date of their arrival at Vietnamese ports. With regard to drugs with the use duration of 24 months or less, their remaining use duration must be at least 12 months, counting from the date of their arrival at Vietnamese ports. In special cases, the Health Ministry shall consider and permit the import of the drugs on a case-by-case basis.

b/ Raw materials imported for production of drugs must have a remaining use duration of more than 3 years, counting from the date of their arrival at Vietnamese ports. With regard to raw materials with the use duration of 3 years or less, the date of their arrival at Vietnamese ports must not be later than 6 months as from the manufacture date. This provision shall not apply to *materia medica*.

4.4. Original assay slips

In carrying out customs clearance procedures, enterprises importing drugs or cosmetics must produce to border-gate customs offices the manufacturers' original assay slips, certifying satisfactory quality standards of each lot of drugs or cosmetics. Border-gate customs offices shall only keep copies of those slips, which bear certification stamps of importing enterprises.

4.5. Intellectual property rights over imported drugs and cosmetics

Traders producing, importing or exporting drugs and/or cosmetics; traders entrusting or being entrusted to import or export drugs and/or cosmetics shall be responsible for intellectual property rights over drugs and/or cosmetics they manufacture, import or export or be entrusted to import or export.

4.6. Making goods orders and dossiers

An order for import or export of drugs and/or cosmetics shall be made in 3 copies according to the form set in this Circular (not printed herein) (with regard to habit-forming finished drugs, psychotropics and pre-substances for use as drugs that have no import registration numbers, a separate order must be made for each type of drug). After such order is approved, 2 copies shall be kept at Vietnam Drug Administration (VDA) and one copy sent to the concerned enterprise. The copy sent to the enterprise shall be affixed with the stamp “Ban gui doanh nghiep” (“for enterprise”), which shall submit it to the border-gate custom office when carrying out customs clearance procedures.

Dossiers and documents enclosed with a goods order must be firmly bound in a dossier set with cover where the name of the importing unit; the number, date of making the order, and the type of the order are clearly inscribed.

4.7. Labels of imported and exported drugs and cosmetics

Labels of imported and exported drugs and cosmetics shall comply with the provisions of the Regulation on the labeling of domestically circulated goods and imported and exported goods, issued together with the Prime Minister’s Decision No. 178/1999/QĐ-TTg of August 30, 1999, and Decision No. 95/2000/QĐ-TTg of August 15, 2000, amending and supplementing a number of contents of this Regulation, and the Health Ministry’s Circular No. 14/2001/TT-BYT of June 26, 2001, guiding the labeling of drugs and cosmetics which directly affect human health, and relevant legal documents.

The printing or sticking of additional labels for drugs imported and circulated in Vietnam shall be as follows:

a/ Additional drug labels may be directly printed or stuck on drug packages by manufacturers.

b/ Where manufacturers have not yet printed or stuck additional drug labels on drug packages, the drugs must be imported into warehouses of importing enterprises for printing or sticking additional labels before circulation.

Where traders entrust the import of drugs, the printing or sticking of additional labels shall be conducted at warehouses of importing enterprises or traders entrusting the import.

c/ Additional labels must not hide information on drug packages and must ensure the following contents:

- With regard to drugs with import registration numbers, additional labels must have all the following contents: full names and addresses (names of provinces and cities) of importing enterprises and import-entrusting traders (if any).

Example 1:

IMPORTING ENTERPRISE: Name of the importing enterprise, its address
IMPORT-ENTRUSTING ENTERPRISE: Name of the import-entrusting enterprise and its address (if any)

IMPORTING ENTERPRISE: Hoang Lan Pharmaceutical Company, Hanoi
IMPORT-ENTRUSTING ENTERPRISE: Thien An Pharmaceutical Limited Liability Company, Ha Tay province

- With regard to habit-forming drugs, psychotropics and pre-substances used as drugs without import registration numbers, additional labels must have all the following contents: full names and addresses (names of provinces or cities) of drug-importing enterprises and import-entrusting traders (if any); serial numbers and issuance dates of import permits.

Example 2:

Importing enterprise: Name of the importing enterprise, its address	IMPORTING ENTERPRISE: Kim Quy Pharmaceutical Company, Hanoi
Import permit No.:.../QLD-... dated.../.../200...	IMPORT PERMIT No.:389/QLD-KD dated April 30, 2004
IMPORT-ENTRUSTING TRADER: Name of the import-entrusting enterprise and its address (if any)	IMPORT-ENTRUSTING TRADER: AB Pharmaceutical Limited Liability Company, Hoa Binh

4.8. Declaration of drug prices

a/ Drug-importing enterprises

- With regard to drugs without import registration numbers, importing enterprises shall, depending on the wholesale or retail of each import item, send together with import goods orders the price lists of imported drugs, which cover import prices of drugs arriving in Vietnam (import duty-exclusive CIF prices), wholesale prices and expected retail prices in Vietnam. Drug prices must be declared in Vietnamese currency (VND) for the smallest packaging unit.

- With regard to finished drugs with registration numbers, in case of a change in their prices compared with the registered prices, importing enterprises must make re-registration with the Health Ministry according to regulations.

b/ Drug import-entrusting traders

Drug import-entrusting traders must supply full and accurate information on prices of drugs of their foreign partners (foreign manufacturers or exporters) to entrusted importing enterprises.

4.9. Reporting

Monthly, importing enterprises must report to the Health Ministry (the Vietnam Drug Administration, the Planning-Finance Department) on the situation of drug import and export in the previous month. The reports must be submitted before the 10th of every month.

4.10. Charges and fees

Enterprises importing drugs and/or cosmetics must pay charges and fees as prescribed by law.

4.11. Validity duration of import permits

An import permit shall be valid for at most one year from the date of its signing.

II. LIST OF DRUGS AND COSMETICS AND FORMS OF MANAGEMENT OF THEIR IMPORT AND EXPORT

1. Drug export

1.1. Habit-forming drugs, psychotropics and pre-substances used as drugs (Appendix 1), which are exported, must have export permits issued by the Health Ministry.

1.2. The export of drugs (except for those specified at Point 1.1 above) shall be effected at customs offices according to current regulations. Where importing countries ask for export permits, the Health Ministry shall issue such permits at the request of enterprises.

2. Import and export of cosmetics

2.1. The export of cosmetics shall be effected at customs offices according to current regulations. Where importing countries ask for export permits, the Health Ministry shall issue such permits at the request of enterprises.

2.2. Cosmetics, which directly affect human health and have already been granted circulation registration numbers by the Health Ministry, shall be imported on demand.

3. Import of drugs

3.1. Raw materials and finished drugs banned from import: Appendix 2.

3.2. Drugs imported on demand which do not require the certification of import orders include finished drugs, raw materials for drug manufacture (except for habit-forming drugs, psychotropics and pre-substances for use as drugs) whose registration numbers are still valid. The detailed lists thereof shall be promulgated by the Vietnam Drug Administration in each period.

3.3. Import drugs requiring import permits of the Health Ministry include:

a/ Habit-forming finished drugs, psychotropics and pre-substances for use as drugs with or without registration numbers, in form of single or mixed substances.

b/ Raw materials for drug manufacture with registration numbers as habit-forming drugs, psychotropics or pre-substances for use as drugs.

c/ Raw materials without registration numbers (including those being habit-forming drugs, psychotropics or pre-substances for use as drugs).

III. DOSSIERS AND PROCEDURES FOR IMPORT OF DRUGS AND COSMETICS

1. Import of drugs with valid circulation registration numbers

1.1. Habit-forming drugs, psychotropics or pre-substances for use as drugs

Importing enterprises shall make goods orders, requesting the grant of import permits, enclosed with reports on unsold drug.

Within seven working days after receiving valid goods orders and dossiers, the Health Ministry shall grant import permits. In case of refusal to issue permits, it must give written replies to enterprises, clearly stating the reasons therefor.

1.2. Other drugs (except those specified at Point 1.1 above)

Importing enterprises shall fill in the customs procedures at border-gate customs offices and produce to the latter goods orders, enclosed with the following documents:

- Product circulation permits or decisions on the grant of circulation registration numbers; documents permitting amendments, supplements or other corrections (if any).

- Foreign drug suppliers' operation licenses for drugs and raw materials for drug manufacture in Vietnam.

2. Import of habit-forming finished drugs, psychotropics and pre-substances for use as drugs without circulation registration numbers

2.1. Conditions

The Health Ministry shall consider the grant of import permits when one of the following conditions is met:

a/ The drugs contain pharmaceutical ingredients of the groups with pharmaceutical effects or officinal forms which have few circulation registration numbers in Vietnam, based on the list of drugs subject to circulation registration numbers promulgated by the Vietnam Drug Administration in each period;

b/ The drugs contain pharmaceutical ingredients without registration numbers in Vietnam:

- The pharmaceutical ingredients have had circulation registration numbers in Vietnam but at the time the import dossiers are submitted, such registration numbers have become invalid or not yet been re-registered;

- The pharmaceutical ingredients have been circulated in other countries in the world but have not had any registration numbers in Vietnam, except for the new ones;

c/ Rare drugs, special-use drugs, specifics or drugs of special officinal forms are imported to meet medical treatment demand;

d/ The drugs are subject to technology transfer or manufactured under license contracts, for which registration dossiers have been submitted and which are awaiting registration numbers;

e/ The drugs are imported on particular medical treatment demands of hospitals (hospitals must make estimation of demanded drug quantities according to the set forms and their directors must make commitments), which shall be supplied to hospitals according to their drug estimations.

f/ Foreign-invested manufacturing enterprises shall be considered for the grant of permits for import of drugs for marketing in the period of manufacture according to regulations of the Trade Ministry and the Health Ministry.

2.2. Import dossiers

Importing enterprises shall make goods orders, requesting the grant of import permits, enclosed with relevant documents, which shall be sent to the Health Ministry (the Vietnam Drug Administration). Such a dossier comprises:

a/ The certificate of pharmaceutical products (CPP) according to WHO's quality certification system, granted by the competent agency of the concerned foreign country. In case of unavailability of such certificate, it may be replaced with free sale certificate (FSC) and goods manufacturing practice (GMP) certificate of the manufacturer, issued by the competent state management agency of the foreign country.

The above certificates must be originals or copies notarized in Vietnam or the foreign country.

b/ Drug quality control criteria and methods.

c/ Two sets of model drug labels (including outer labels, intermediate labels and inner labels) and written use instructions, affixed with the stamp of the importing enterprise, specifically:

- The model of the original label of the drug circulated in the foreign country. Where the language in such label is other than English or French, a label design for import into Vietnam must be submitted with English or Vietnamese translation.

- The written use instruction (01 original and 01 Vietnamese version). With regard to a drug made from materia medica and traditional medicaments, the written use instruction must be in Vietnamese, stating all ingredients of the drug and the names of medicinal ingredients must be written in both Vietnamese and Latin languages.

d/ The price list of the imported drugs.

e/ The report on unsold drugs.

f/ With regard to pharmaceutical ingredients which have been already circulated in other countries but haven't had any Vietnamese registration numbers, the dossiers on their pharmaceutical effects and clinical research are required.

g/ With regard to drugs imported on particular demands of a hospital:

- A separate goods order is required, clearly stating that it is based on the hospital's particular demand.

- The hospital's drug demand estimation.

- The hospital director's written commitment that the drugs shall be used within the hospital only according to the drug estimate.

- The dossiers specified at Items a, b, c, d, e and f, Point 2.2 above. In special cases where the hospital needs to use drugs with active substances, concentration, content or official forms which have no registration numbers in Vietnam but have been mentioned in professional documents, whereby the enterprise cannot supply the dossiers defined at Items a, b, c, d, e and f, Point 2.2 above, the following documents must be enclosed with:

- + The enterprise's written request for import of the drugs to meet the hospital's particular medical treatment demand, stating the reasons for failure to supply dossiers on the imported drugs according to regulations, and commitments on the quality of the imported drugs.

- + The report on the use of drugs (use demand, safety, treatment effect) and commitments of the hospital's director for the receipt and reasonable and safe use of the drugs.

2.3. Permit-granting procedures

Within 20 working days after receiving goods orders and valid dossiers, the Health Ministry shall consider to grant import permits. In case of refusal to grant permits, it must give written replies, clearly stating the reasons therefor.

3. Import of raw materials without circulation registration numbers for drug manufacture

3.1. Import dossier

Importing enterprises shall request the grant of import permits, enclosed with related dossiers and send them to the Health Ministry (the Vietnam Drug Administration). Such a dossier comprises:

a/ The import goods order.

b/ The quality standards and raw material-assay methods, for raw materials subject to manufacturers' quality standards and assay methods, which are affixed with the certification stamp of the importing enterprise. This provision is not compulsory for materia medica.

c/ With regard to raw materials for manufacture of drugs being habit-forming drugs, psychotropics or pre-substances, a report on unsold goods is required.

3.2. Permit-granting procedures

Within 7 working days after receiving valid goods order and dossiers, the Health Ministry shall consider to grant import permits. In case of refusal to grant permits, it must give written replies to enterprises, clearly stating the reasons therefor.

4. Import of drugs and cosmetics in other special cases

4.1. Import of drugs for epidemics or natural disaster prevention and fight

A dossier shall comprise:

a/ The drug import order.

b/ The importing enterprise's written request for import of drugs in service of epidemic, natural disaster prevention and fight, with certification by a state management body in charge of public health.

4.2. Import of drugs under national health programs or projects:

A dossier shall comprise:

a/ The drug import order.

b/ The enclosed documents, including legal documents on the import of drugs under national health programs or projects.

c/ The import of drugs under national health programs or projects must be entrusted to enterprises with function to import drugs directly. Drug labels must bear the line "drugs under national health program" or "drugs under national health project".

4.3. Import of drugs and cosmetics as samples for circulation registration

A dossier shall comprise:

a/ The import goods order.

b/ Each type of finished drugs or cosmetics must be imported with no less than 5 packing units, compatible with the samples of those expected to be put in circulation.

c/ Raw materials for drug manufacture shall be imported each with one pack and the weight of each pack shall be sufficient for 3 assays, compatible with each type of raw materials.

4.4. Import of drugs for assay and production research

A dossier shall comprise:

a/ The import goods order.

b/ The Health Ministry shall consider the import of drugs with specific volume, suitable to the import objective.

IV. DOSSIERS AND PROCEDURES FOR EXPORT OF DRUGS AND COSMETICS

1. Export of habit-forming drugs, psychotropics and pre-substances for use as drugs:

1.1. Habit-forming drugs, psychotropics and pre-substances for use as drugs that have registration numbers in form of single or mixed substances

A dossier shall comprise:

a/ The export goods order.

b/ The import permit granted by the competent agency of the importing country.

1.2. Habit-forming drugs, psychotropics and pre-substances used as drugs in form of single or mixed substances without registration numbers

A dossier shall comprise:

a/ The export goods order.

b/ The import permit, granted by the competent agency of the importing country.

c/ The enterprise's commitment to comply with the export contract and not to circulate products that have not yet been granted circulation registration numbers by the Health Ministry. The enterprise's director shall take responsibility for the quality of, and intellectual property rights over, exported drugs.

2. Other drugs (except for habit-forming drugs, psychotropics and pre-substances used as drugs) and cosmetics

The export thereof shall be effected at customs offices according to current regulations. Where importing countries have demand and at the request of exporting enterprises, the export of drugs and cosmetics shall be conducted as follows:

2.1. Export of drugs

a/ The list of export drugs.

b/ The enclosed dossiers, as specified at Item c, Point 1.2, Section 1, Part IV of this Circular.

2.2. Export of cosmetics

The export goods order is required.

3. Permit-granting procedures

Within 7 working days after receiving valid goods orders and dossiers, the Health Ministry shall grant export permits at the request of enterprises. In case of refusal to grant permits, it must give written replies, clearly stating the reasons therefor.

V. ORGANIZATION OF IMPLEMENTATION AND HANDLING OF VIOLATIONS

1. The Vietnam Drug Administration shall, within the ambit of its competence, receive and evaluate dossiers and grant permits for import or export of drugs and cosmetics.

2. The Health Ministry's Inspectorate shall coordinate with the Ministry's functional departments in inspecting, examining and handling according to law violations on drug prices as well as those in the import and export of drugs and cosmetics nationwide.

3. Inspectorates of provincial/municipal Health Services shall organize inspection, examination and handle violations on drug prices and those in the import and export of drugs and cosmetics in their respective provinces or cities.

4. Enterprises involved in the import and/or export of drugs and cosmetics, that violate the provisions of this Circular shall, depending on the severity of their violations, be administratively sanctioned or be considered by the Health Ministry for suspension of the grant of import or export permits for between 6 months and 1 year or shall be examined for penal liability according to the provisions of law; if causing damage, they must pay compensation according to relevant provisions of law.

VI. IMPLEMENTATION PROVISIONS

1. Goods orders for the import of drugs and raw materials for drug manufacture without registration numbers, which have been granted import permits by the Health Ministry (the Vietnam Drug Administration) as from January 1, 2006, and remained valid until April 30, 2006, shall be extended till September 30, 2006.

2. List of drugs with registration numbers already certified by the Health Ministry (the Vietnam Drug Administration) in the period from January 1, 2006, to April 30, 2006, and remained valid until April 30, 2006, shall be extended as follows:

- Till September 30, 2006, for drugs whose registration numbers are valid until after September 30, 2006.

- Till the expiry date of the registration number, for drugs whose registration numbers' validity duration falls in the period from the effective date of this Circular to September 30, 2006.

3. This Circular takes effect 15 days after its publication in "CONG BAO", annulling the previous regulations contrary thereto.

4. The Vietnam Drug Administration, units attached to the Health Ministry, provincial/municipal Health Services, Vietnam Pharmaceutical Corporation, enterprises importing and/or exporting drugs and/or cosmetics, foreign companies having operation licenses in pharmacy, medical treatment establishments, and drug assay institutions shall have to implement this Circular.

In the course of implementation, concerned units are requested to report difficulties and problems to the Health Ministry (the Vietnam Drug Administration) for consideration and settlement.

Minister

of

Health

TRAN THI TRUNG CHIEN