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Regulations on the Administration of Precursor Chemicals

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No. 445

The Regulations on the Administration of Precursor Chemicals, which were adopted at the 102nd executive meeting of the State Council on August 17th, 2005, are hereby promulgated and shall go into effect as of November 1st, 2005.

the Premier of the State Council Wen Jiabao

August 26, 2005

Regulations on the Administration of Precursor Chemicals

Chapter I General Provisions

Article 1 For the purpose of strengthening the administration of precursor chemicals, regulating the production, distribution, purchase, transportation and import and export of precursor chemicals, preventing precursor chemicals from being used in manufacturing drugs and maintaining the economic and social order, the present Regulations are formulated.

Article 2 The state adopts the classified administration and licensing system to the production, distribution, purchase, transportation and import and export of precursor chemicals.

The precursor chemicals are classified into three categories. Category I includes the major materials that can be used for producing drugs. Categories II and III include the chemical agents that can be used for producing drugs. The detailed classification and types of precursor chemicals are shown in the annex of the present Regulation.

In case the classification or types of precursor chemicals need to be adjusted, the public security department of the State Council shall, in conjunction with the supervisory and administrative department of food and drugs, the supervisory and administrative department of safe production, the competent commerce department, the competent health department of the State Council and the General Administration of Customs, put forward a proposal and report it to the State Council for approval.

In case the people's government of the province, autonomous region or municipality directly under the Central Government deems it necessary to adjust the classification of precursor chemicals or to add any other type other than those as prescribed in the present Regulations within its administrative jurisdiction, it shall propose this to the public security department of the State Council. The public security department of the State Council shall put forward a proposal, and shall, in conjunction with the relevant competent administrative departments of the State Council, report it to the State Council for approval.

Article 3 The public security department, the supervisory and administrative department of food and drugs, the supervisory and administrative department of safe production, the competent commerce department, the competent health department, the General Administration of Customs, the competent pricing department, the competent railway department, the competent communications department, the administrative department for industry and commerce and the competent environmental protection department of the State Council shall, within the scope of their respective authority, be responsible for the relevant administration of precursor chemicals throughout the country. The relevant competent administrative departments of all the people's governments at or above the county level shall, within the scope of their respective authority, be responsible for the relevant administration of the precursor chemicals within their respective administrative jurisdictions.

All the people's governments at or above the county level shall strengthen their leadership in the administration of precursor chemicals, and coordinate to timely solve the problems arising from the administration of precursor chemicals.

Article 4 The product name (including the scientific name and the common name), chemical molecular formula and ingredients of the chemical liable to producing drugs shall be clearly indicated on its packaging and instructions.

Article 5 The production, distribution, purchase, transportation and import and export of precursor chemicals shall comply with the relevant provisions of the

present Regulations. And if the precursor chemicals belong to pharmaceuticals or dangerous chemicals, the relevant provisions of the laws and other administrative regulations on pharmaceuticals and dangerous chemicals shall be complied with as well.

It's prohibited to smuggle or illegally produce, operate, purchase, transfer or transport any chemical liable to producing drugs.

It's prohibited to trade precursor chemicals in cash or kind, however, an individual may legally purchase the pharmaceutical preparations of precursor chemicals under the item of pharmaceuticals in Category I or the precursor chemicals in Category III.

An entity that produces, distributes, purchases, transports, imports or exports the precursor chemicals shall establish an internal management system for precursor chemicals.

Article 6 The state encourages informants to inform the relevant competent administrative departments, such as the public security organs, of any illegal activities related to precursor chemicals. The department that receives a tip-off shall keep secret the relevant informant. If the tip-off turns out to be true, the people's government at or above the county level and the relevant competent administrative department shall award the relevant informant.

Chapter II Management of Production and Distribution

Article 7 An entity that applies for production of precursor chemicals in Category I, shall satisfy the following conditions and may start production only after it has obtained the production license upon the examination and approval of the competent administrative department as prescribed in Article 8 of the present Regulations :

- (1) Having been legally registered as a production enterprise of chemical products or pharmaceuticals;
- (2) Having the production equipments, warehouse facilities and pollutant disposal facilities that conform to the state standards;
- (3) Having a strict safe production management system and a prepared plan for environmental emergencies;
- (4) The legal representative and the technical and management personnel of the enterprise having the relevant knowledge of safe production and precursor chemicals, and having no record of drug-related crimes.
- (5) Other conditions as prescribed by laws, regulations and rules.

An entity that applies for production of precursor chemicals under the item of pharmaceuticals in Category I shall not only satisfy the above-mentioned conditions, but also install, in key areas such as warehousing places, the video monitors and the alarm devices networked with the public security organ.

Article 8 An application for the production of precursor chemicals under the item of pharmaceuticals in Category I shall be subject to the examination and approval of the supervisory and administrative department of food and drugs of the State Council. An application for the production of precursor chemicals under any item in Category I other than pharmaceuticals shall be subject to the examination and approval of the supervisory and administrative department of safe production of the people's government of the province, autonomous region or municipality directly under the Central Government.

The competent administrative departments as prescribed in the preceding paragraph shall, within 60 days as of the day of receipt of an application, examine the application materials as submitted by the applicant. If the applicant satisfies the relevant provisions, it shall issue a production license to the applicant or give an indication on the relevant production license obtained by the relevant enterprise. In the case of disapproval, it shall notify, in writing, the applicant of the reasons therefore.

When examining the application materials for the production license of precursor chemicals in Category I, the competent administrative departments may, where necessary, organize an on-site inspection and expert review.

Article 9 An entity that applies for the distribution of precursor chemicals in Category I, shall satisfy the following conditions and may start business operation only after it has obtained the distribution license upon the examination and approval of the competent administrative department as prescribed in Article 10 of the present Regulations:

- (1) Having been legally registered as a distribution enterprise of chemical products or pharmaceuticals;
- (2) Having a business place that conforms to the provisions of the state, and if the precursor chemicals need be stored or kept, having the warehouse facilities that conform to the technical standards of the state as well;
- (3) Having an management system and a sound sales network for the distribution of precursor chemicals;
- (4) The legal representative and the technical and management personnel of the enterprise having the relevant knowledge of precursor chemicals and having no record of drug-related crimes; and
- (5) Other conditions as prescribed by laws, regulations and rules.

Article 10 An application for the distribution of the precursor chemicals under the item of pharmaceuticals in Category I shall be subject to the examination and approval of the supervisory and administrative department of food and drugs of the State Council. An application for the distribution of the precursor chemicals under any item in Category I other than pharmaceuticals shall be subject to the examination and approval of the supervisory and administrative department of safe production of the people's government of the province, autonomous region or municipality directly under the Central Government.

The competent administrative departments as prescribed in the preceding paragraph shall, within 30 days as of the day of receipt of an application, examine the application materials as submitted by the applicant. Where the applicant satisfies the relevant provisions, it shall issue a distribution license to the applicant or give an indication on the relevant business license that has been obtained by the relevant enterprise. In the case of disapproval, it shall notify, in writing, the applicant of the reasons therefore.

When conduct an examination on the application materials for distribution license for the precursor chemicals in Category I, the competent administrative departments may, where necessary, organize an on-site inspection.

Article 11 A production enterprise, which has obtained the production license for precursor chemicals in Category I or has gone through the record-keeping formalities for the production of precursor chemicals in Category II or III under the provisions of paragraph 1 of Article 13 of the present Regulations, may

distribute the precursor chemicals it produces. However, where an enterprise is to establish sales outlets outside its factory for the distribution of precursor chemicals in Category I, it shall obtain the distribution license in accordance with the provisions of the present Regulations.

The single preparations of precursor chemicals under the item of pharmaceuticals in Category I shall be distributed by the designated distribution enterprise of narcotic drugs and may not be retailed.

Article 12 An enterprise that has obtained the production or distribution license for precursor chemicals in Category I shall, upon the strength of its production or distribution license, register the alteration of its business scope with the administrative department for industry and commerce. No enterprise may produce or distribute the precursor chemicals in Category I unless the alteration of business scope has been registered.

Where the production or distribution license for precursor chemicals in Category I is revoked pursuant to the law, the competent administrative department shall, within 5 days after making the decision on revocation, inform the administrative department for industry and commerce. The enterprise whose license has been revoked shall timely register the alteration of its business scope or nullify its registration with the administrative department for industry and commerce.

Article 13 An enterprise that produces the precursor chemicals in Category II or III shall, within 30 days as of the day of starting production, file such information as the type and quantity for record, with the supervisory and administrative department of safe production of the municipal people's government of the districted city where it is located.

An enterprise that distributes the precursor chemicals in Category II shall, within 30 days as of the day of starting distribution, file such information as the type, quantity and major flow direction for record, with the supervisory and administrative department of safe production of the municipal people's government of the districted city where it is located. An enterprise that distributes the precursor chemicals in Category III shall, within 30 days as of the day of starting distribution, file such information as the type, quantity and major flow direction for record, with the supervisory and administrative department of safe production of local people's government of the county where it is located.

The competent administrative departments as prescribed in the preceding two paragraphs shall issue the record-keeping certification on the very day when it receives the materials submitted for record.

Chapter III Administration of Purchase

Article 14 An entity that applies for purchasing the precursor chemicals in Category I shall submit the following certificates to the competent administrative department as prescribed in Article 15 of the present Regulations for examination and approval, and obtain the purchase license therefrom upon approval:

- (1) As for a distribution enterprise, the business license and the certification of its need for legal use and ;
- (2) As for other organizations, the certificate of registration (approval document of establishment) and the certification of its need for legal use .

Article 15 With regard to the application for purchasing precursor chemicals under the item of pharmaceuticals in Category I, it shall be subject to the examination and approval of the supervisory and administrative department of food and drugs of the people's government of the province, autonomous region or municipality directly under the Central Government where the applicant is located. With regard to the application for purchasing precursor chemicals under any item in Category I other than pharmaceuticals, it shall be subject to the examination and approval of the public security organ of the people's government of the province, autonomous region or municipality directly under the Central Government where the applicant is located.

The competent administrative departments as prescribed in the preceding paragraph shall, within 10 days as of the day of receipt of an application, examine the application materials and certificates as submitted by the applicant. Where the applicant satisfies the relevant provisions, it shall issue a purchase license to the applicant; in the case of disapproval, it shall notify, in writing, the applicant of the reasons therefore.

When examining the application materials for purchasing precursor chemicals in Category I, the competent administrative departments may, where necessary, conduct an on-site inspection.

Article 16 Where a medical institution, which holds the seal card for purchasing narcotic and psychotropic pharmaceuticals in Category I, purchases the precursor chemicals under the item of pharmaceuticals in Category I, it need not apply for the purchase license for precursor chemicals in Category I.

No individual may purchase any chemical liable to producing drugs in Category I or II.

Article 17 An entity that is to purchase any chemical liable to producing drugs in Category II or III shall, prior to the purchase, file an information about the type and quantity in demand for record, with the public security organ of the local people's government at the county level. Any purchase of potassium permanganate of small quantity by an individual for self-use need not be put on record.

Article 18 A distribution entity, when selling the precursor chemicals in Category I, shall examine the purchase license and the proof of identity of the handling person. In the case of an entrusted purchase, it shall examine the power of attorney as held by the purchaser as well.

A distribution entity may sell the precursor chemicals in Category I only if no error is found through the examination and after the photocopies of the above-mentioned materials are kept. Upon discovery of any suspicious circumstance, it shall immediately report it to the local public security organ.

Article 19 A distribution entity shall maintain a ledger for the sale of precursor chemicals and faithfully record the varieties, quantities, date and purchasers on the precursor chemicals sold. The sales ledger and photocopies of certification materials shall be preserved for 2 years for future reference and inspection.

The sales information of precursor chemicals in Category I shall be submitted, within 5 days as of the day of sale, to the local public security organ for record. An entity that uses the precursor chemicals in Category I shall maintain a use ledger and preserve it for 2 years for future reference and inspection.

The sales information of precursor chemicals in Category II or III shall be submitted, within 30 days as of the day of sale, to the local public security organ for record.

Chapter IV Administration of Transportation

Article 20 Where the transportation of precursor chemicals in Category I is across two or more the administrative areas at the level of districted cities (or across boundaries of a municipality in the case of municipalities directly under the Central Government) or across two or more administrative areas at the level of counties

within the key areas where the anti-drug situation is severe, which are determined by the public security department of the State Council, it shall be subject to the examination and approval of the public security organ of the municipal people's government of the departure city which is divided into districts. The transportation of precursor chemicals in Category II shall be subject to the examination and approval of the public security organ of the people's government at the level of the departure county. No transportation may be conducted until the transportation license for precursor chemicals is granted upon examination.

The transportation of precursor chemicals in Category III shall, prior to departure, be filed for record with the local public security organ of the people's government at the level of county where the transportation starts; and the public security organ shall issue the record-keeping certification at the very day when it receives the materials submitted for record.

Article 21 As for an application for the transportation of precursor chemicals, the contract on purchase and sale of precursor chemicals shall be submitted. If the owner is an enterprise, its business license shall be submitted. If the owner is any other organization, the certificate of registration (approval document of establishment) shall be submitted. If the owner is an individual, his identity certificate shall be submitted. The individual who directly carries out the transportation shall submit his identity certificate.

The public security organ shall, within 10 days as of the day of receipt of the application for the transportation license for precursor chemicals in Category I, or within 3 days as of the day of receipt of the application for the transportation license for precursor chemicals in Category II, examine the application materials submitted by an applicant. If the applicant satisfies the relevant provisions, it shall issue the transportation license to the applicant. In the case of disapproval, it shall notify, in writing, the applicant of the reasons therefore.

When necessary, an on-site examination may be conducted in examining the application materials for the transportation license for precursor chemicals in Category I.

Article 22 Where the transportation of precursor chemicals in Category I is approved, a transportation license valid for once shall be issued.

Where the transportation of precursor chemicals in Category II is approved, a transportation license valid for 3 months shall be issued; and where the transportation condition is safe and sound for 6 months, a transportation license valid for 12 months shall be issued.

Such matters as the type, quantity, destination, owner and consignee, and the carrier of the precursor chemicals to be transported as well as the type of the transportation license shall be clearly indicated in the transportation license for precursor chemicals.

Article 23 For the transportation of the ephedrine samples of less than 100g for the purpose of teaching or scientific research, or the small package ephedrine as used by medical institutions for the preparation and prescription, or the ephedrine of not more than 60, 000 pills or 15, 000 injection preparations as purchased by a medical institution or a narcotic drugs distributor, where the owner or carrier holds the purchase license or the allocating list of narcotic drugs as obtained according to law, it need not apply for the transportation license for precursor chemicals.

Article 24 When accepting the consignment from a owner, a carrier shall examine the transportation license or record-keeping certification provided by the owner, and verify whether or not the freight is consistent with the type of precursor chemicals and other information that are specified in the transportation license or the record-keeping certification. If it is found to be inconsistent, no goods may be transported.

In the transportation of precursor chemicals, the transportation personnel shall carry with them the transportation license or the record-keeping certification throughout the transportation period from the departure. The public security organ shall conduct inspections during the course of transportation of precursor chemicals.

The transportation of precursor chemicals shall comply with the provisions of the State on freight transportation.

Article 25 For the need of treatment of diseases, a patient, his near relative or the person as entrusted by the patient may, upon the strength of the medical diagnosis issued by a medical institution and his proof of identity, carry with him the medical preparation of precursor chemicals under the item of pharmaceuticals in Category I, provided it does not exceed the maximum dosage in a single medical prescription.

Chapter V Administration of Import and Export

Article 26 Anyone who applies for the import or export of precursor chemicals shall submit the following materials and may engage in the import or export of precursor chemicals only after it has obtained the import or export license upon the examination and approval of the competent commerce department of the State Council or the competent commerce department of the province, autonomous region or the municipality directly under the Central Government as authorized thereby:

- (1)The photocopy of the registration certification of the foreign trade operator (the certification of annual joint examination for foreign-funded enterprises);
- (2)The duplicate of the business license;
- (3)The licenses or the record-keeping certification for production, distribution, or purchase of precursor chemicals;
- (4)The duplicate of the import or export contract (agreement); and
- (5)The identity certificate of the handling person.

Anyone who applies for the export license of precursor chemicals shall, in addition, submit the certification of legal use of precursor chemicals as issued by the competent governmental department of the region where the importer is located or the guaranty documents as provided by the importer on the legal use of precursor chemicals.

Article 27 The competent commerce department that accepts the application for the import and export of precursor chemicals shall, within 20 days as of the day of receipt of the application materials, examine the application materials and may, when necessary, conduct on-site inspection. If the applicant satisfies the relevant provisions, the competent commerce department shall issue the import or export license. If no license is granted, it shall notify, in writing, the applicant of the reasons therefore.

As for the import of precursor chemicals under the item of pharmaceuticals in Category I, the relevant competent commerce department shall obtain the consent of

the supervisory and administrative department of food and drugs of the State Council before making any decision on licensing.

Article 28 Ephedrine and other precursor chemicals falling within the scope of special control shall be imported or exported only by the enterprises as jointly verified by the competent commerce department of the State Council and the relevant departments of the State Council.

Article 29 The state adopts an international check-up system to the import and export of precursor chemicals. The catalogue of precursor chemicals subject to international check-up and the specific measures for check-up shall be formulated and promulgated by the competent commerce department of the State Council in conjunction with the public security department of the State Council.

The time used for the international examination may not be included into the time limit for licensing.

For the export of precursor chemicals and the chemicals other than those as provided by the present Regulations to a country or area where the illicit manufacture or trafficking of drugs is severe, other control measures may be taken in addition to the international check-up measures. The concrete measures shall be formulated and promulgated by the competent commerce department of the State Council in conjunction with the public security department of the State Council, the General Administration of Customs and other relevant departments.

Article 30 As for the import, export, transition, transshipment or through transportation of precursor chemicals, declaration shall be faithfully made to the customs and the import or export license shall be submitted thereto. The customs shall handle the clearance formalities according to the relevant license.

The provisions of the preceding paragraph shall be applicable to the import and export of precursor chemicals between overseas areas and the areas under special supervision of the customs or bonded areas, such as bonded zones and export processing zones.

As for the import and export of precursor chemicals between the areas within the territory of China and the areas under special supervision of the customs or bonded areas, such as bonded zones and export processing zones, or between the aforesaid areas under special supervision of the customs and bonded zones, it is not required to apply for the import or export license of precursor chemicals.

As for the import of precursor chemicals under the item of pharmaceuticals in Category I, the customs clearance notice of imported pharmaceuticals as issued by the supervisory and administrative department of food and drugs shall be submitted in addition.

Article 31 The pharmaceutical preparations of precursor chemicals under the item of pharmaceuticals in Category I or potassium permanganate carried by individuals entering and exiting the territory of China shall be limited to a reasonable amount for self-use and shall be subject to the supervision of the customs. Any individual entering and exiting the territory of China may not carry with him any precursor chemicals other than those as set out in the preceding paragraph.

Chapter VI Supervision and Inspection

Article 32 The public security organs, the supervisory and administrative departments of food and drugs, the supervisory and administrative departments of safe production, the competent commerce departments, the competent health department, the competent pricing departments, the competent railway departments, the competent communications departments, the administrative departments for industry and commerce, the competent environmental protection departments of the people's government above the county level as well as the customs shall, in accordance with the present Regulations and the provisions of the relevant laws and administrative regulations, and within their respective authorities, strengthen the supervision and inspection of the manufacture, distribution, purchase, transportation, price and import and export of precursor chemicals, and shall, according to law, investigate into and deal with illegal manufacture, distribution, purchase and transportation of precursor chemicals or any smuggling of precursor chemicals.

When carrying out the supervision and inspection of precursor chemicals, the competent administrative departments as prescribed in the preceding paragraph may, according to law, inspect the scene, consult and copy the relevant materials, record the relevant information, detain the relevant evidence materials and illicit articles, and may seal up the relevant place temporarily when necessary.

Any entity or individual under inspection shall faithfully provide the relevant information, materials and articles and may not refuse to provide and conceal them.

Article 33 The precursor chemicals as captured and seized according to law shall be preserved and reclaimed in light of different conditions of the precursor chemicals under the supervision of the public security organ or the administrative environmental protection department of the people's government of the province, autonomous region, municipality directly under the Central Government or the districted city or under the supervision of the customs, or shall, in accordance with the relevant provisions of laws and administrative regulations on environmental protection, be destroyed by a qualified entity under the supervision of the administrative environmental protection department. In particular, the precursor chemicals under the item of pharmaceuticals in Category I as captured and seized shall be all destroyed.

Where an entity or individual that violates the relevant provisions on the precursor chemicals is unable to afford the expenses for the prevention, reclamation or destruction of the precursor chemicals concerned, such expenses shall be paid from the income as derived from the reclamation or shall be allotted in the anti-drug expenses of the relevant competent administrative department.

Article 34 Where precursor chemicals are lost, stolen or robbed, the entity concerned shall immediately report the case to the local public security organ and, at the same time, to the supervisory and administrative department of food and drugs, the supervisory and administrative department of safe production, the competent commerce department or the competent health department of the local people's government at the county level. The public security organ that receives the report shall immediately file the case and conduct investigations and shall report it to the public security organ at a higher level. The relevant competent administrative department shall report the case level by level and shall coordinate with the public security organ in the investigation.

Article 35 The relevant competent administrative department shall notify the relevant public security organ and the administrative department for industry and commerce of any issuance or revocation of the license of precursor chemicals according to law. The administrative department for industry and commerce shall notify the relevant public security organ and the competent administrative department of any alteration or cancellation of registration of the enterprises that engage in the production or distribution of precursor chemicals.

Article 36 An entity that produces, distributes, purchases, transports, imports or exports the precursor chemicals shall, prior to March 31st of each year, report the

information about the production, distribution, purchase, transportation or import or export of precursor chemicals in the previous year, to the competent administrative department and the public security organ that grant the licensing or accept the materials submitted for record. An entity that produces, distributes, purchases, transports, imports or exports the precursor chemicals may, where the conditions permit, establish a computer network connected with the relevant competent administrative departments so as to timely report the relevant information on its business operation.

Article 37 The relevant competent administrative departments of the people's government at or above the county level shall intensify the coordination and cooperation and establish a mechanism for circulating and exchanging the information on the administration, supervision and inspection of precursor chemicals as well as on the handling of relevant cases .

Chapter VII Legal Liabilities

Article 38 Where an entity, in violation of the provisions of the present Regulations, engages in any production, distribution, purchase or transportation of precursor chemicals without license or filing relevant materials for record, forges application materials to cheat for the license of production, distribution, purchase or transportation, undertakes the production, distribution, purchase or transportation of precursor chemicals by using other's license or a forged, altered or invalid license, the public security organ shall confiscate the precursor chemicals illicitly produced, distributed, purchased or transported, the raw materials for illicit production of precursor chemicals and the equipments and tools for the illicit production, distribution, purchase or transportation of the precursor chemicals; and it shall impose a fine of not less than 10 times but not more than 20 times of the value of the precursor chemicals illicitly produced, distributed, purchased or transported. In case 20 times of such value is less than 10, 000 Yuan, the fine shall be 10, 000 Yuan. The relevant illicit gains, if any, shall be confiscated. If the violator has a business license, such business license shall be revoked by the administrative department for industry and commerce. If a crime is constituted, the relevant violator shall be investigated for criminal liabilities according to law.

As for an entity or individual that commits an irregular acts as prescribed in the preceding paragraph, the relevant competent administrative department may, within 3 years as of the day when administrative punishment is made, cease to accept its/his application for the license for production, distribution, purchase, transportation or import or export of precursor chemicals.

Article 39 Where an entity or individual, in violation of the provisions of the present Regulations, smuggles the precursor chemicals, the customs shall confiscate the precursor chemicals and the illicit gains, if any, and it shall impose an administrative sanction upon the violator in accordance with the customs laws and administrative regulations. If a crime is constituted, the relevant violator shall be investigated for criminal liabilities according to law.

Article 40 Where an entity, in violation of the provisions of the present Regulations, commits any of the following acts, the competent administrative department responsible for supervision and administration shall give it a warning and order it to make corrections within a prescribed time limit and impose a fine of not less than 10, 000 Yuan but not more than 50, 000 Yuan; and it may confiscate the precursor chemicals that are illicitly produced, distributed or purchased. If the violator fails to make corrections within the prescribed time limit, it shall be ordered to suspend its production and distribution for rectification within a prescribed time limit; and if the rectification is not made as required within the prescribed time limit, its relevant license shall be revoked:

- (1)An entity that produces, distributes, purchases, transports or imports or exports the precursor chemicals fails to establish a safety management system as required;
- (2)Lending its license or record-keeping certification to others;
- (3)Producing, distributing or purchasing any precursor chemicals beyond the bound of licensed type and quantity;
- (4)An entity that produces, distributes, purchases the precursor chemicals fails to record or to faithfully record the transaction information , or fails to keep the record of transaction as required or to timely and faithfully file the sales information for record with the public security organ and the relevant competent administrative departments;
- (5)Failing to make a timely report when the precursor chemicals are lost, stolen or robbed, and thus causing serious consequences;
- (6)Conducting transactions in cash or kind of any chemical liable to producing drugs other than those under the item of pharmaceuticals in Category I and those in Category III that may legally purchased by individuals;
- (7)The product packaging or instructions of precursor chemicals does not comply with the provisions of the present Regulations; or
- (8)An entity that produces, distributes, purchases the precursor chemicals fails to make annual report of its production, sales or inventory to the relevant competent administrative department and the public security organ faithful and timely.

Where an enterprise fails to timely alter its business scope or cancel its registration with the administrative department for industry and commerce after its business license for production and distribution of precursor chemicals is revoked pursuant to law, the precursor chemicals concerned shall be confiscated and a fine shall be imposed upon the enterprise according to the provisions of the preceding paragraph.

Article 41 Where the type, quantity, destination, owner, consignee or carrier of precursor chemicals in transportation is not in line with what is indicated in the transportation license or record-keeping certification for precursor chemicals, or where the type of the transportation license is improper or where the transportation personnel fail to carry with them the transportation license or record-keeping certification throughout the course of the transportation, the public security organ shall order the violator to cease the transportation for rectification, impose a fine of not less than 5, 000 Yuan to but not more than 50, 000 Yuan. If the violator has the qualifications for transportation of dangerous articles, the competent transportation department may disqualify it from transporting dangerous articles according to law.

Where an individual carries precursor chemicals at variance with the specified type or quantity, the precursor chemicals shall be confiscated and a fine of not less than 1, 000 Yuan but not more than 5, 000 Yuan shall be imposed upon the violator.

Article 42 Where an entity or individual that produces, distributes, purchases, transports or imports or exports precursor chemicals refuses to accept the supervision and inspection conducted by the relevant competent administrative department, the competent administrative department responsible for supervision and administration shall order it/him to make corrections and give a warning to the person-in-charge directly responsible and other personnel directly liable. If the

circumstances are serious, a fine of not less than 10,000 Yuan but not more than 50,000 Yuan shall be imposed upon the entity, and a fine of not less than 1,000 Yuan but not more than 5,000 Yuan shall be imposed upon the person-in-charge directly responsible and other personnel directly liable. If a violation of the administration of public security is constituted, an administrative penalty for public security shall be imposed in accordance with the law. If a crime is constituted, the relevant violator shall be investigated for criminal liabilities according to law.

Article 43 Where a functionary of the competent administrative department in charge of precursor chemicals, in his/her administrative work, refuses to grant license to those qualified or abusively grants license to those unqualified, fails to accept the materials for record according to law, or commits other illicit acts by abusing his power, neglecting his duty or practicing favoritism for selfish interests, he shall be given an administrative sanction according to law; and if a crime is constituted, the relevant violator shall be investigated for criminal liabilities according to law.

Chapter VIII Supplementary Provisions

Article 44 The relevant competent administrative departments of the State Council shall, according to their respective functions and duties, specify the formats of the licenses for production, distribution, purchase, transportation and import or export of precursor chemicals and shall supervise the production of such licenses.

Article 45 The present Regulations shall go into effect as of November 1, 2005.

An entity that has engaged in the production, distribution, purchase, transportation or import or export of precursor chemicals prior to the effective day of the present Regulations shall, within 6 months as of implementation of the present Regulations, file a new application for corresponding license according to the provisions of the present Regulations.

Annex

Catalogue of Classification and types of Precursor chemicals

Category I

- 1-phenyl-2-propanone
- 3,4-Methylenedioxyphenyl-2-propanone
- peronal
- safrole
- sassafras oil
- iso-safrole
- n-acetyl o-amino benzoic acid
- o-amino benzoic acid
- ergotic acid*
- ergotamine*
- ergobasine*
- ephedrine, pseudo ephedrine, mesoephedrine, phenylpropanolamine, methylephedrine, ephedrine extractum, ephedrine extractum powder and other ephedrine substances

Category II

- phenyl acetic acid
- acetic oxide
- chloroform
- aether
- piperidine

Category III

- toluene
- acetic oxide acetone
- methyl ether ketone
- potassium permanganate
- sulphuric acid
- hydrochloric acid

Notes:

- The saline chemicals that may exist in the substances as listed in Category I or II shall be brought into control.
- The types marked with "*" are precursor chemicals under the item of pharmaceuticals in Category I, which include the pharmaceutical raw materials and the single preparation thereof.

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