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LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative text / texts

MACAO SPECIAL ADMINISTRATIVE REGION OF CHINA

Communicated by the Government of China

Note by the Secretariat

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non relevant parts or laws and regulations have been deleted by the Secretariat, such deletions are indicated by […].

Decree-Law 34/99/M on Combating the Trafficking and Taking of Narcotics and Psychotropic Substances

V.05-80274 (E)

DECREE-LAW 34/99/M ON COMBATING THE TRAFFICKING AND TAKING OF NARCOTICS AND PSYCHOTROPIC SUBSTANCES

CHAPTER I

General Provisions

Article 1

Objectives and Scope of Application

1. This Act prescribes the rules on the control of the legal market of the narcotic drugs and psychotropic substances as listed in tables 1-4 (hereinafter referred to as the tables) attached to Decree No 5/91/M of 28th, January.[1]
2. Planting, production, manufacturing, use, re-packing, trading, marketing, import, export, transportation, and possession and use, under any pretext, of the plants, substances or preparations listed in tables 1-4 shall be subject to limitation, approval and supervision as stipulated in this Act.

Article 2

Definitions

For the validity of this Act and under the precondition of no influence upon the definitions specified in international conventions on narcotic drugs and psychotropic substances, the following definitions shall apply throughout this Act:

"Production" means obtainment of narcotic drugs or psychotropic substances from natural organic substances by way of collection or extraction.

"Manufacture" means all processes by which narcotic or psychotropic substances may be obtained, and includes refining as well as the transformation of products into other products.

"Preparation" means processes of transformation of narcotic drugs or psychotropic substances with physical or chemical methods.

"Import" means transfer of narcotic drugs or psychotropic substances into this region, excluding direct trafficking.

"Export" means transfer of narcotic drugs or psychotropic substances out of this region, excluding direct trafficking. Re-export shall be taken as the same to export.

"Direct trafficking" means transportation or relay of narcotic drugs or psychotropic substances via Macao for the exclusive purpose of carrying these goods to destinations specified in the documents attached to them.

"Wholesaling" means purchase of narcotic drugs or psychotropic substances in personal name and with self-owned funds and sale of these goods to other wholesalers, retailers, processors, or specialized users.

[1] Note by the Secretariat: The sample forms are available with the Secretariat but have not been reproduced here.

Article 3

Rules on Interpretation

All the technical prescriptions and concepts as used in this Act shall be interpreted in accordance with conventions on narcotic drugs and psychotropic substances that are applicable in Macao.

Article 4

Obligation to Provide Reference Materials

As required by the Sanitation Department of Macao (SSM in brief in Portuguese), all entities licensed to engage in activities specified in Clause 2, Article 1 shall provide relevant reference materials to the Department within prescribed limits of time.

Article 5

Competence

1. SSM shall be the only entity in Macao empowered to grant, revoke or terminate approvals as specified in this Act.
2. SSM is also empowered to:
   a) Supervise licensed activities without affecting the power granted to police entities;
   b) Ensure the strict observance of the international obligations, especially observance of the conventions and protocols on narcotic drugs and psychotropic substances;
   c) Collect reference materials on narcotic drugs and psychotropic substances in accordance with international conventions, and compile and produce reports and forms for submission to international organs;
   d) Compile and approve models of prescription and registration forms and graphs and tables, and promulgate rules for observance when these documents are filled and kept;
   e) Control the use of prescriptions;
   f) Organize registration of natural and legal persons licensed to engage in activities specified in this Act, and record punishments dealt to these natural and legal persons in registration forms; and
   g) Initiate law procedures against, investigate and punish law-breaking acts, and report facts that may be counted as criminally illicit acts to entities empowered to implement criminal proceedings.
3. When exercising its power of supervision, SSM shall give technical instructions to activities to be undertaken with approval.

Article 6

Supervision

1. When exercising its power of supervision as specified in the preceding article, SSM shall carry out at any time inspection of the enterprises, sites or spots engaging in activities specified in Clause 2, Article 1, and shall require presentation of necessary documents or registrations.

2. If any entity refuses to present documents or registrations as demanded, SSM shall seek aid from police authorities to enforce the measures. At the same time, it shall take other measures to ensure the effect of its inspections and report the case without affecting the validity of the stipulations in Article 20 of Decree No 5/91/M of 28th, January.
3. Cases of illicit behaviors shall be reported to entities empowered to carry out criminal investigations upon their discovery, or to SSM if these illicit behaviors are purely administrative.

Article 7

Emergency Report

1. Should any substances or preparations listed in the tables referred to in Article 1 be taken away or lost, the entities taking care of these substances or preparations shall report in writing the cases to SSM within 24 hours after occurrence of the events to give detailed descriptions of the occurrence of the events, specify accurately the amount and features of the lost substances or preparations, and provide whatever evidences they can.
2. Reports shall also be made to police authorities within the time limits and according to stipulations specified in the preceding clause whenever any of the cases mentioned above occurs.

Article 8

Supply of Substances or Preparations to Transportation Tools

1. SSM shall permit ships, aircraft and other international public transportation tools to engage in international traffic of small amounts of substances and preparations listed in Table 1-A, Table 2-B, Table 2-C, Table 3 and Table 4 for first-aid purposes during their journey.
2. The amount of the substances and preparations mentioned above shall not exceed the amount as may be needed for approval purposes under normal conditions, and shall be carried in safe conditions to avoid being taken away or lost.
3. Applications for supply of the substances or preparations listed in Clause 1 shall be signed by the physician stationed in the ships or aircraft, or by the physician stationed in enterprises concerned if no physicians are stationed in these ships or aircraft. The applications shall specify the names and serial numbers of the ships or aircraft, the departments or places of their registration, the security measures to be taken, and the persons to take care and keep these substances or preparations.
4. The persons taking care and keeping these substances or preparations, as mentioned in the preceding clause, shall make written statements of their readiness to assume relevant responsibilities.
5. The substances and preparations to be carried according to stipulations in Clause 1 shall be subject to the laws, regulations, permits, and licenses of the countries with which the transportation tools are registered, without prejudice to any rights of the local authorities to carry out checks, inspections and other control measures on board these ships or aircraft.

Article 9

International Flow of Persons

1. Persons entering into or departing from Macao may carry substances or preparations listed in Table 1-A, Table 2-B, Table 2-C, Table 3 and Table 4 for personal use. The amount shall be kept, however, under the maximum needed for treatment for no more than 30 days. Documents containing explanations by physicians of the purpose of these substances or preparations shall also be presented.
2. If no documents containing explanations by physicians of the purposes of the substances or preparations are presented, as specified in the preceding clause, the need to use the substances or preparations referred to in the preceding clause shall be confirmed by public health authorities.
3. If no documents containing explanations by physicians of the purposes of the substances or preparations are presented, as mentioned above, the customs authorities shall detain any of the substances or preparations specified in the preceding clause. If SSM refuses to acknowledge the need of use, the customs authorities shall detain these substances or preparations.

CHAPTER II

Approval, Restriction and Control

SECTION 1

Approval

Article 10

General Provisions

1. The director of SSM shall be empowered to instruct the granting, revocation or termination of approval of engagement in activities specified in Clause 2, Article 1.
2. Approval shall be granted if the following two requirements are met:
   a. The activities applied for approval meet the need of this region; and
   b. The substances or preparations are to be used for the purpose of treatment, scientific study, analysis, or teaching. This excludes, however, the exceptions specified in the convention referred to in Article 3.

Article 11

Application for Approval

1. Any application for approval shall be filed to the director of SSM. An application shall contain the following:

   a) Materials recognizing the entity that has signed the application together with other relevant documents of recognition;

   b) Specification of the responsible druggist, or the person in charge of completion and care of the registration in case of absence of a responsible druggist;

   c) A statement signed by the entity mentioned above announcing its readiness to assume responsibility over the completion and care of the registration and over its performance of duties;

d) Certificates of the criminal records of the applicant and the persons in charge referred to in the two items above, or in the case of a legal person, a certificate of the criminal records of the person that can make the legal person to assume its obligations.

2. Each enterprise, its branch(es), affiliate(s), or work spot(s) shall submit an application.
3. Omissions in an application shall be supplied within 60 days at the longest. If they are not supplied within the prescribed time limit, the application shall be refused.

Article 12

Subjective Requirements

1. Approval shall be granted to an entity only when it is fully guaranteed that the owner or agent of this entity is morally excellent and professionally integral.
2. When only the public interest of guarantee of public health and combating of trafficking of narcotic drugs and psychotropic substances is taken into consideration, such morality and integrity as mentioned in the preceding clause shall be evaluated according to the contents of criminal records.
3. Hospitals shall be exempted from presentation of certificates of criminal records.

Article 13

Decision on Approval or Disapproval

1. Approval shall not be transferred, or be conceded to or used by others under any pretext.
2. The term of validity of a general approval shall be one year, and may be extended for a term of similar length if applied for by the person of interest within 60 days before expiration of its validity.
3. A special grant shall remain valid only within the time limit set in a decision, and shall not exceed one year.
4. All decisions on approval shall be published in the Gazette of the Government. Apart from the conditions stipulated in this Act and other applicable laws and regulations, a decision shall specify special conditions for observance by the applicant. The term of approval shall start from the date of publication.
5. In case the director of SSM makes a decision of disapproval, appeals may be lodged to an administrative court.

Article 14

Revocation of Approval

1. An approval shall be revoked in case any of the following facts concerning the entity that has won the approval occurs:

   a) Expiration of the term of approval without extension of the term according to stipulations in Clause 2 of the preceding article;

   b) Termination of relevant activities;

   c) Termination of the legal person that has won the approval;

d) Change of the name of the business or the company, or removal of facilities;

e) Death of obligee;

f) Transfer of the ownership or operations of an enterprise in any name, especially mortgage or concession of a site to operation by others;

g) Replacement of the agent of the legal person that has won the approval; and

h) Failure to pay costs payable according to stipulations in this Act.

2. SSM shall announce the revocation of approvals and publish such announcements in the Gazette of Macao Government.

Article 15

Maintenance of Approval

1. In case of events involving items d) to g) in Clause 1 of the preceding article, an application shall be filed for maintaining the approval of engagement in relevant activities.
2. Applications for the maintenance of approvals shall be submitted within 60 days, and, as is required by circumstances, shall be composed of documents certifying transfers, replacements of obligees, changes of the names of businesses, or removals of facilities; and/or certificates of deaths.
3. Whether or not an approval is to be maintained shall be determined by satisfaction of the requirements on moral excellence and professional integrity as set in Article 12.

Article 16

Revocation and Termination of Approval

1. If the requirements set for the granting of an approval no longer exist, or in case of violation of stipulations in Clause 1, Article 13, the director of SSM shall immediately revoke a given approval, while other kinds of punishments may be meted out nevertheless.
2. If the responsible druggist or the person in charge of compilation and keeping of registrations can not attend his/her businesses for the time being for some reason and has to authorize another druggist or person who promises to assume the responsibility instead, the approved activities can be carried on for 60 days at the longest. If the above-mentioned situation of inability to attend businesses for some reason continues after expiration of the time limit, the approval shall be revoked.
3. In case of occurrence of the following events, an approval shall be revoked or terminated for a maximum length of six months:

   a) Technical accidents;

   b) Subtraction or damage of substances or preparations;

   c) Occurrence of events that may actually harm public health or lead to illicit supply at markets, or any other events that violate regulations; and

   d) Failure to fulfill the obligations the beneficiary of an approval is obliged to.

4. Decisions on the revocation or termination of approvals shall be published in the Gazette of Macao Government.

5. Appeals may be lodged to an administrative court concerning the decisions by the director of SSM, as is referred to in this article.

Article 17

Disposal of Stocks

1. When a license becomes invalid or is revoked or terminated, SSM shall permit, upon application by the person of interest, the return of stocks of substances or preparations listed in tables 1-4 to their original suppliers, drug stores, or other licensed entities.
2. A return application shall be filed within 30 days starting from the date of decision on the revocation or termination of a license, or from the date of publication of the invalidity of a license.
3. If an appeal is lodged, the time limit mentioned above shall start from the date of notification of decision on the hearing of the appeal.
4. The application as referred to in Clause 2 shall be accompanied by announcements of agreement by entities or drug stores of interest and inventories detailing the substances or preparations to be returned or conceded. The names, types, contents, amounts, batch numbers, and time of efficacy of the substances or preparations shall be specified in the inventories.
5. If no application is filed for substances or preparations returns according to stipulations in Clause 1 upon expiration of the time limit specified in Clause 2, or if a return application is refused, stocks shall be counted and deposited in a sealed room of an enterprise or at any other sites designated by the director of SSM. If the substances or preparations face any danger of damage or flow into illicit markets, the director of SSM shall permit their sale or destruction, and hand over the revenues from such sales to the owners of these substances or preparations after deducting locally sustained costs.
6. Any destruction shall be overseen by a committee composed of three members appointed by the director of SSM. This committee shall take and sign relevant written notes in which the substances or preparations being destroyed and the amount involved shall be specified.

Article 18

Notification of Approval

1. SSM shall notify the Department of Justice and Police, the Security Corps, and the Waterborne Patrol Police (PMF in brief in Portuguese) of its approval of engagement in activities specified in Clause 2, Article 1, and call their attention to the restrictions and requisites specified in the approval.
2. Decisions on the extension, termination or revocation of licenses and announcements of invalidity of licenses shall also be made known to the police entities mentioned above.
3. SSM shall notify departments taking charge of prevention and treatment of drug addiction of its decisions on the granting, extension, termination or revocation of licenses as well as announcements of invalidity of licenses.

SECTION II

Growing, Production and Manufacturing

Article 19

Prohibition of Growing

It shall be prohibited to grow the plants listed in Table 1 and Table 2.

Article 20

Extraction and Manufacturing

1. For the purpose of development of medical and veterinary science and scientific study, chemical and pharmaceutical licenses shall be issued appropriately for the extraction, conversion or manufacturing of the substances or preparations listed in tables 1-4.
2. For the purpose mentioned in the preceding clause, it shall be permitted to extract or manufacture, by way of synthesis, alkaloid of the plant species listed in Table – A, Table – B and Table – C.
3. Manufacturing of the substances listed in Table 2 – A shall be permitted only for the purpose of scientific study.
4. Applications for licenses shall be composed of materials specified in Clause 2, Article 11 and materials listed blow:

   a) Descriptions of manufacturing sites, manufactured substances, and locations of deposits of manufactured substances or preparations, and relevant safety conditions;

   b) Identification data of responsible druggists;

   c) Indications of the substances and preparations to be manufactured, their output, destinations, and processes of extraction and manufacturing; and

   d) Explanations about the nature and quantity of the raw materials to be needed in manufacturing.
5. Raw materials can be obtained and stored, and manufactured goods can be sold on the strength of manufacturing licenses. Such sales shall be made, however, only to licensed entities.
6. Terms shall be set in decisions on the granting of licenses so that SSM can prevent the storage of narcotic drugs and psychotropic substances in greater quantities than is needed at the market or than is needed for the normal operation of applicant entities.

Article 21

Quotas for the Manufacturing of Substances

1. In each July, SSM shall fix the quotas for the manufacturing and marketing of the substances listed in Table 1 and Table 2, excluding those listed in Table 2 – A, for the following year by taking into consideration its international pledges and in accordance with the rules in relevant conventions.
2. The quotas fixed according to stipulations in the preceding clause shall be subject to re-arrangement, even if such re-arrangements may lead to reviews of licenses that are still valid during the use of these re-arranged quotas.

3. As may be required by special circumstances, SSM shall be empowered to promptly impose restrictions on the manufacturing of special substances or preparations.
4. The quotas fixed according to stipulations in Clause 1 and their re-arrangement shall be published in the Gazette of Macao Government.

SECTION III

Wholesaling and Distribution

Article 22

Authorization of Wholesaling

1. Wholesaling of the substances and preparations listed in tables 1-4, excluding those listed in Table 2 –A, shall be conducted only by entities licensed to handle the import, export and wholesaling of pharmaceutical products.
2. Apart from the materials listed in Article 11, applications for approval of engagement in the business mentioned in the preceding clause shall also contain information on the following:

   a) The locations of the enterprises to be engaged in the business and their branches, affiliates, or operating sites;

   b) The special sites for receiving, storing, distributing and delivering products;

   c) The safety measures already taken or to be taken; and

   d) The substances and preparations to be traded.
3. Requirements shall be set in decisions granting approval to engagement in the said business so that SSM can prevent storage of narcotic drugs or psychotropic substances in greater quantities than is needed at the market or than is needed for the normal operation of the applicant entities.

Article 23

Marketing or Conceding of Substances and Preparations

1. When the substances or preparations listed in tables 1-4 are to be sold or conceded to hospitals, drug stores or any other legally licensed entities, the sales or concessions shall be conducted on the strength of order-placing forms whose sample is provided in Appendix 1 which constitutes a component part of this Act, or documents of equal effect sent out with information tools. This does not apply, however, to the substances and preparations listed in Table 2 – A.
2. The above-mentioned procedures shall not apply to the sale or concession of the substances or preparations listed in Table 3 by licensed wholesaling entities to public or privately-run hospitals.
3. Prior approval shall be obtained from SSM if samples of the preparations listed in Table 4 are to be mailed or delivered to physicians or veterinarians.
4. Applications for obtaining the above-mentioned approval shall contain the following information:

   a) Identification data of the applicants;

b) Identification data of the conceding entities;

c) Commercial names of the substances or preparations involved;

d) Ingredients, forms, and gross quantities of each pack; and

e) Purposes.

5. It is prohibited to mail or deliver samples of the substances or preparations listed in Table 1, Table 2 and Table 3.

Article 24

Order-placing Documents

1. The order-placing document mentioned in Clause 1 of the preceding article shall be composed of two samples marked respectively as A and B. Sample A accompanied by the receipt shall be held by the order placer, and sample B accompanied by a copy of the receipt shall be held by the supplier.
2. Each order shall be placed for one kind of substances or preparations.

Article 25

Procedures of Delivery

1. Delivery of the substances and preparations listed in tables 1-4, excluding those listed in Table 2 – A, shall be conducted only in one of the following forms:

   a) If the substances or preparations are delivered in person to a licensed obligee, a druggist, an authorized agent, or a responsible person appointed by an entity, as is specified in Clause 1, Article 23, the name, serial number of the identification card, and other reliable identification data of the receiver shall be put onto the blank margin of the order-placing form; and

   b) Or the substances or preparations shall be delivered by transportation companies or privately-run postal companies.
2. Whenever more than one kilogram of the substances listed in Table 1 is to be transported, the supplier shall give the police authorities a written notice in advance.
3. The names of the supplier and the receiver, the tools to be used for transportation, the date and time of transportation, and the nature and quantity of the substances to be transported shall all be specified in the notice mentioned above.
4. The notice, to be prepared in three workdays' advance, shall be made in triplicate. One of the sample copies shall be held by the police authorities, another shall be sent by the police authorities to a local authority competent of jurisdiction of the area where the substances are destined, and the third sample copy, signed by the police authorities, shall be sent by the receiver back to the supplier together with the goods.

Article 26

Documents Pertaining to Supply

1. If goods are delivered by a transportation company or by a privately-run postal company, the supplier shall keep Sample B of the order-placing form and other receiving documents for a period of five years, while the order placer shall be obliged to keep Sample A of the order-placing form for a same period of time.
2. All activities of sales and concessions shall be recorded in documents whose Sample II and Sample III are provided by SSM and contained in Appendix 1 of this Act.
3. The documents mentioned above shall carry the latest information and be communicated to SSM at the end of each quarter.

Article 27

Supply for Special Purposes

1. SSM shall permit the supply of the substances and preparations listed in Table 1 – A, Table 2 – B, Table 2 – C and Table 4 to:

   a) Entities lawfully licensed to keep hold of these substances or preparations for use in study, which shall also be permitted to get supply of the substances listed in the other tables; and

   b) Ships, aircraft, and other international transportation tools, although such supply shall be conducted in accordance with stipulations in Article 8.
2. The supplier and the person taking care and keeping the substances or preparations shall be specified in the application, along with descriptions of the safety measures to be taken.
3. If a supply is made on the strength of a signed and verified order form, this order form shall be attached to a document certifying approval of the said supply.
4. The amount of the substances or preparations to be supplied shall not exceed the ceiling set for the need to fulfill the approval purpose under normal conditions.
5. Under the prerequisite of observing the general conditions, it shall be permitted to supply the substances and preparations listed in Table 1 – A to departments in charge of prevention and treatment of drug addiction so that they can use substitutes of narcotics to prescribe treatment.

SECTION IV

Import, Export and Transit

Article 28

Import and Export

1. Import and export of the substances and preparations listed in tables 1-4 shall be handled by firms specializing in the import, export or wholesaling of pharmaceutical products or by the pharmaceutical sector. This shall not affect the application, however, of the stipulations in the following clauses:
2. Hospital institutions shall be permitted to import substances and preparations for medical treatment, scientific study, and teaching purposes.

3. The chemical sector and the pharmaceutical sector shall be permitted to import substances and preparations for business purposes only, or to export substances or preparations made with these imported substances or preparations.
4. Each case shall be approved separately. If the actual amount of the substances or preparations involved is smaller than the approved quota, the said quota may be put into fulfillment, although no packaging differing from that specified in the license shall be used.

Article 29

Application of Prior Approval

1. Prior approval for the import or export of the substances or preparations listed in tables 1-4 shall be applied for with Sample IV and Sample V attached in Appendix 1 of this Act.
2. An application for prior approval of exports shall also be accompanied by an import license issued by the authorities of the country to which the goods are destined.
3. Application for prior approval shall be filed at least three workdays before the date of conduction of imports or exports.

Article 30

Import and Export Certificates

1. If required by a dealing country, SSM shall issue an import certificate according to Sample VI and Sample VII attached in Appendix 1 of this Act, or an export certificate according to Sample VIII and Sample IX attached in Appendix 1 of this Act.
2. Each certificate shall be produced in five sample copies to be submitted to, respectively, the SSM, the applicant, the authorized entity of the dealing country, the International Narcotics Control Board, and the customs institution of the area of entry or exit.

Article 31

Forms of Export to Be Prohibited

1. Export of the substances or preparations listed in tables 1-4 by mailing them to a bank or a postal box to a party other than the party named in the authorization shall be prohibited.
2. Export of the above-mentioned substances or preparations to a customs warehouse shall also be prohibited unless the government of the importing country certifies on the import certificate that it has approved the placement of the substances or preparations in such a warehouse.
3. If substances or preparations are exported to a customs warehouse according to stipulations in the preceding clause, it shall be indicated on the export certificate that the said warehouse shall be the destination of the said substances or preparations.
4. Exporter of the substances or preparations referred to in Article 1 shall strictly ensure that the seal is broken before the opening of the packaging.

Article 32

Application of Approval for Transit

1. Transit of any of the substances or preparations referred to in Article 1 shall be handled only by businesses specializing in the import, export or wholesaling of pharmaceutical products.
2. Apart from the documents specified in Article 11, applications for authorization of transit of the substances or preparations listed in tables 1-4 via Macao shall also be accompanied by import certificates issued by the authorities of the destination countries and export certificates issued by the authorities of the countries of origin. This need not apply, however, to those listed in Table 2 – A.
3. If approval is obtained for changing the original country of destination of consignments, the transit of the said goods shall be subject to restrictions of the export system.

Article 33

Notification to PMF

Approval of import or export of the substances or preparations listed in tables 1-4 shall be notified to PMF.

Article 34

Inspection by PMF

1. PMF shall thoroughly identify and exercise control over consignments of import, export or transit according to the notes carried in relevant authorizations.
2. PMF shall have the right to take necessary measures to prevent the carriage of any substances or preparations to a destination other than that specified in the duplicate of the export certificate accompanying a consignment.
3. No procedures shall be gone through that may change the nature of the substances or preparations listed in tables 1-4 that are kept in a customs warehouse on their way of transit. Nor shall the packaging of the said substances or preparations be altered without approval from the exporting country. This need not apply, however, to the substances and preparations listed in Table 2 – A.
4. Import consignments shall be delivered by PMF to the receiver under the presence of the representatives of SSM's inspection department.
5. Delivery of the substances or preparations listed in Table 1 shall be made by filling Sample X attached in Appendix 1 of this Act.
6. When carrying out inspection, samples of the substances or preparations shall be collected for the purpose of making analysis. The results of such inspections shall be reported to SSM.

Article 35

Documents for the Relevant Activities

1. Activities of import and export shall be registered in Sample II and Sample III provided by SSM in Appendix 1 of this Act.

2. The documents mentioned in the preceding clause contain the latest information and shall be reported to SSM at the end of each quarter.
3. Documents pertaining to imports and exports shall be put on the file separately and kept for five years.

Article 36

Other Measures and Restrictions

The Governor shall, as suggested by SSM or police entities, instruct the prohibition or termination of engagement in activities specified in Clause 2, Article 1, or set other conditions or restrictions for the import, export or transit of the substances or preparations listed in tables 1-4, so long as these measures can appropriately guarantee public health and prevent illicit traffic of psychotropic substances.

SECTION V

Supply, Prescription and Dispensation

Article 37

Supply of Drugs

1. The substances and preparations listed in tables 1-4 shall be supplied only by pharmacies and hospitals. This need not apply, however, to those listed in Table 2 – A.
2. The substances listed in Table 2 – A shall be supplied by hospitals.

Article 38

Prescription by Physician

1. The substances and preparations listed in Table 1, Table 2 and Table 4 shall be supplied to the general public for the purpose of medical treatment only on the strength of prescriptions produced by physicians or veterinarians according to samples 10 to 16 in Appendix 2, which constitute a component part of this Act. This need not apply, however, to the substances listed in Table 2 – A.
2. The substance listed in Table 2 – A shall be supplied to entities authorized by law to hold these substances for the purpose of scientific study only on the strength of prescriptions produced by physicians or veterinarians according to the form approved by SSM.
3. The yellow prescription in Sample XI and the green prescription in Sample XII shall both be made in quadruplicate. The stubs shall be kept by the physicians and put on the file for three years.
4. Pursuant to stipulations in Clause 2, Article 42, the original of the prescriptions shall be sent to SSM for the collection of fees, the second copy shall be kept at the pharmacies, the third copy shall be sent to SSM, and the fourth copy shall be given to drug acquirers.

5. The yellow prescriptions in Sample XIII and Sample XV and the green prescriptions in Sample XIV and Sample XVI shall be produced in triplicate by public or private institutions specializing in the supply of health-care services respectively. The stubs of these prescriptions shall be kept by physicians, veterinarians, or persons in charge of keeping the prescriptions, and put on the file for three years.
6. The original of these prescriptions shall be sent to SSM as is prescribed in Clause 2, Article 42, the second copy shall be kept in the pharmacies, and the third copy shall be given to drug acquirers.
7. Pharmacies shall arrange the second copy of prescriptions according to their dates of production and put them on the file for five years.
8. Each prescription involving any of the substances or preparations listed in Table 1 and Table 2 shall administer only one drug, except when the substances listed in Table 2 – A are involved. In case the substances or preparations listed in Table 4 are involved, each prescription may contain three kinds of drugs at the most.
9. Pursuant to stipulations in Article 44 of Decree No 58/90/M of 19th, September, preparations listed in Table 3 shall be supplied only on the strength of prescriptions produced by physicians.

Article 39

Dispensing of Prescriptions

1. Technical executives dispensing prescriptions involving narcotic or psychotropic substances shall verify the correct filling of prescriptions, mark the dates of dispensing, and sign prescriptions in a readable manner.
2. Apart from observing the stipulations in the preceding clause, technical executives dispensing prescriptions administering narcotic or psychotropic substances listed in Table 2 – B and Table 2 – C shall also put the names and the serial numbers and dates of issuance of the identification cards, residence permits or driving licenses of the acquirers on the originals of the prescriptions and ask the acquirers to sign the prescriptions. In case the acquirers are foreigners, the serial numbers and dates of issuance of their passports shall be put onto the prescriptions with their signatures.
3. In order to identify acquirers, technical executives shall also accept other kinds of documents. These documents shall carry, however, the photos of the holders, and the acquirers shall be asked to sign.
4. In case acquirers do not understand or are unable to sign, the technical executives shall make notes of the circumstance.
5. Technical executives shall refuse to dispense prescriptions containing narcotic or psychotropic substances in any of the following cases:
   a) When a prescription is not produced according to the sample approved by SSM;
   b) When a prescription is not properly filled;
   c) When the authenticity of a prescription is suspected;
   d) When a prescription was produced five days ago; and
   e) When a prescription has already been dispensed.

6. In case of c) of the preceding clause, the technical executives shall try his/her utmost to contact the physician or veterinarian, with the cost to be borne by the acquirer.
7. The prescriptions referred in this article shall be dispensed by acting druggists only when technical executives are obviously incompetent of dispensing.

Article 40

Cases of Necessity

1. In case of necessity and absence of a physician for prescription, a druggist may supply the substances or preparations listed in tables 1-4 for immediate take so long as the total amount is kept below the maximum dosage for one service and the druggist assumes responsibility over such supply. This need not apply, however, to the substances listed in Table 2 – A.
2. Supply of substances or preparations in accordance with stipulations in the preceding clause shall be registered separately in the space reserved for this purpose in the book specified in Clause 1, Article 48, or be put on relevant records of an information character.
3. Technical executives shall notify SSM, within three workdays, of supplies made according to stipulations in this article, and identify the acquirers, patients and drugs according to the information carried in the sample specified in Clause 1, Article 38.

Article 41

Prohibition of Delivery to Psychotics or Minors

1. Delivery of substances or preparations listed in tables 1-4 to persons obviously suffering from mental disorder and minors shall be prohibited.
2. In case an incompetent person does not have an attorney, delivery shall be made to the person taking care of this incompetent person or responsible for the education or care of this incompetent person.
3. The druggist dispensing a prescription according to stipulations in the preceding clause shall indicate on the original of the prescription the person receiving the substances or preparations and ask the person to sign. In case the person does not understand or is unable to sign, a note shall be made of the circumstance.

Article 42

Distribution and Control of Prescriptions

1. SSM shall have the right to distribute prescribing books according to actual needs of administration of prescriptions and charge relevant fees according to the table in Appendix 3, which constitutes a component part of this Act.
2. Pharmacies and public and private health institutions shall keep the second copy of prescriptions. In the case of prescriptions produced according to Sample XI or Sample XII, the original and third copy of each prescription shall be sent to SSM before the eighth date of the month following the date of dispensing the prescription, at the latest. In the case of prescriptions produced according to samples XIII-XVI, the originals shall be sent to SSM within the time limit set above.

3. If it discovers any cases of abnormal take of narcotics or psychotropic substances administered in prescriptions produced by private physicians or by unidentified physicians, SSM shall have the right to take necessary measures to amend such abnormal situation.
4. The price of prescribing books shall be regulated by decrees.

Article 43

Public and Private Health Institutions

In public and private health institutions, druggists or persons in charge of medical facilities shall exercise control of the substances and preparations listed in tables 1-4, and take the responsibility of sending inventories of narcotic drugs and psychotropic substances used for the purpose of medical treatment to SSM in each quarter. The inventories shall be prepared according to Sample XVII and Sample XVIII attached to Appendix 1 or in the form of information documents of equal effect.

Article 44

Professional Nursing Staff

Professional nursing staff taking up jobs in this region according to law shall supply the substances and preparations listed in tables 1-4 only on the strength of prescriptions administered by physicians.

SECTION IV

Registration and Safety

Article 45

Registration

1. The registries referred to in this chapter shall conform with the sample approved in the decree, with each page being numbered and signed by SSM. They shall also carry notes on the start and termination of their use.
2. No blanks shall be left in a registry, and no inscriptions, alterations or corrections shall be allowed between the lines unless with announcements of alterations. Registration shall be made in the sequence of time and numbered in the sequence of order.
3. Entities authorized to manufacture the substances or preparations listed in Table 1, Table 2 and Table 4 shall keep all of their registrations for five years starting from the last registration.
4. In other cases, the time for keeping all registrations shall be three years starting from the last registration.
5. SSM shall have the right to supervise and control of the registration.
6. SSM shall allow registration on information carriers instead of registration on solid carriers in traditional use so long as the authenticity and safety of the information is not affected.

Article 46

Obligation to Register

1. All the import and export of the substances and preparations listed in Table 1, Table 2 and Table 4 shall be registered according to stipulations in the preceding article.
2. The use of registries and other records of an information character shall be terminated on 31st, December of each year. At the time of termination, the total amount of the substances and preparations in storage, the sum total of the substances and preparations put into use in the current year, and the difference between the amount of the substances and preparations registered in the current year and that of the substances and preparations registered in the past shall be indicated.

Article 47

Registration of Import, Export and Manufacturing Processes

1. Entities authorized to manufacture the substances and preparations in tables 1-4 shall enter information about the import, export, start of manufacturing, and processes of manufacturing of these substances and preparations in registries or records of an information character. This need not apply, however, to the substances listed in Table 2 – A.
2. Registration of the export and the start of manufacturing of the substances and preparations shall carry the serial numbers of registration of the export of the substances.
3. The substances obtained during the period of manufacturing shall also be registered as imported substances, even if they have been obtained by way of synthesis. These registrations shall carry information relating to the information recorded in the registrations of manufacturing.
4. Any change in the amount of the stocks of any substances shall be calculated in special columns. Registration of the processes leading to such changes shall be indicated in these columns.
5. Registries of manufacturing processes shall carry complete information on the identification of products and the origins and amount of the raw materials that have been used, and indicate the names of the raw materials involved, the dates of their importation into manufacturing departments, and the quantities and relevant batch numbers of the finished products.

Article 48

Registration of Prescriptions

1. Pharmacies shall prepare special registries or relevant records of an information character for registering the prescriptions that they dispense and involve the substances or preparations listed in Table 1, Table 2 and Table 4.
2. The following information shall be recorded in the registries or records of an information character mentioned in the preceding clause:
   a) The serial numbers of the prescriptions;
   b) The commercial names of the substances or preparations concerned;
   c) Their contents and quantities;

d) The forms of the drugs;

e) The names of the physicians or veterinarians producing the prescriptions;

f) The names of the patients or the owners of the animals;

g) Identification data of the acquirers;

h) Dates of delivery; and

i) The names of persons dispensing the prescriptions.

3. The responsible persons concerned shall terminate the use of registries of information records on 31st, December of each year.
4. The stipulations in the preceding clause shall be applicable to public health departments and private health institutions with special pharmacies.
5. The supplies as referred to in Article 40 shall be registered in the special sections of registries.

Article 49

Report of Cases of Subtractions or Losses

In case of subtraction, loss or nullification of any of the registries, records of an information character, order forms, or prescribing books under their keeping, the entities involved shall immediately report the cases to local police authorities and SSM in writing to give detailed accounts of relevant facts and indicate the serial numbers of the documents wherever possible.

Article 50

Security Obligations

1. All institutions authorized in accordance with stipulations in this Act to hold the substances or preparations listed in tables 1-4 shall take appropriate security measures to prevent the loss or subtraction of the said substances or preparations.
2. The entities mentioned above shall adopt the measures of technical protection worked out for them by SSM.
3. Those who refuse to adopt these measures shall have their authorization revoked without any prejudice to the imposition of other fines.

SECTION IIV

Advertising, Packaging and Labeling

Article 51

Prohibition of Advertising

Advertising pertaining to the substances or preparations listed in tables 1-4 shall be prohibited, excluding advertising in technical publications and in information carriers targeted at specialists working in the public health sector.

Article 52

Packaging and Labeling

1. SSM shall work out safety regulations on the opening of containers for packing the substances and preparations listed in tables 1-4.
2. The labels attached to the containers of the substances or preparations listed in the various tables referred to in the preceding clause that are put on sale shall, apart from carrying information required by other laws and regulations, indicate in Portuguese and Chinese the weight or the proportional amount of the substances contained therein and their internationally used names as provided by the World Health Organization.
3. If the substances or preparations may lead to addiction by the takers, this fact shall be indicated in the labels and the instructions going with the drugs. The warning "Drug addiction may be resulted" shall also be given in red.
4. Instructions going with containers shall carry the following information:
   a) The commercial and common names of the drugs;
   b) Modes of treatment;
   c) Indication;
   d) Dosage;
   e) Side effects, adverse reaction, contraindication, and interaction;
   f) Symptoms of overuse;
   g) Package and content; and
   h) Methods for keeping and other matters for special attention

SECTION VIII

Fees

Article 53

Fees

1. Fees as specified in Appendix 4 of this Act shall be paid for the application of general and special authorizations, and of extension of the authorization of engagement in activities referred in Clause 2, Article 1. This appendix is an integral part of this Act.
2. Apart from the fees mentioned above, no other service charges or fees shall be charged.
3. Public legal persons shall be exempted from payment of all service charges or fees.
4. Standards on the fees shall be regulated by decrees.

Article 54

Form and Time Limit of Payment

1. The fees mentioned in the preceding clause shall constitute a part of the revenues of the region and shall be paid in the following forms:

a) The fees for the application of general or special authorizations shall be paid by 50 per cent at the time of submission of applications, with the remaining sums to be paid within 15 days after the persons of interest are notified of decisions on authorizations.

b) The fees for the extension of authorizations shall be paid at the time of submission of applications.

2. Those failing to pay the fees with the time limit set in the preceding clause shall make extra pays amounting to 10 per cent of the fees due.
3. An authorization shall become invalid, with the records being put on the file, if payment of relevant fees is not completed 30 days after expiration of the time limit set for the payment of the said fees.
4. If an application is refused or the records are put on the file, the fees already paid shall not be returned.

CHAPTER III

Punishment

Article 55

General Principles

1. Acts committed in violation of the provisions of this Act or disobedience of the restrictions or obligations set in authorizations shall constitute an offence against the law punishable according to the articles below.
2. Infliction of the punishments specified in this chapter shall not exempt violators from civil or criminal responsibilities, or save them from other punishments that shall be meted out to them according to other laws or regulations.
3. In case of negligence, the fines to be imposed shall not exceed half of the maximum fines set for a relevant offence against the law.
4. Legal persons and entities equal to legal persons shall hold responsibility over fines imposed upon those holding posts in them for committing an offence against the law when performing their duties, but will not influence the personal responsibilities of the violators.
5. No punishments shall be meted out to violators before the conduction of hearings. Punishments meted out otherwise shall be null and void.
6. Punishments shall be administered according to instructions from the director of SSM.

Article 56

Payment of Fines

1. The time limit set for the payment of fines is 15 days starting from the date of communication of a notice of the decision on the punishment.
2. If fines are not paid voluntarily within the time limit set in the preceding clause, collection shall be enforced by entities in the capacity according to the execution procedures for compulsory taxation.
3. Certificates of decision on the administration of punishments shall be used as the basis of such execution.

4. Appeals may be lodged to an administrative court against any imposition of fines.

Article 57

Accumulative Offence

1. Committing the same offence against the law within one year after the decision on the administration of punishments shall be regarded as an accumulative offence.
2. Both the minimum and the maximum fines to be imposed on those with an accumulative offence shall be doubled.

Article 58

Time Effect

1. The time effect of the procedures for administering the punishments referred to in this Act shall be one year starting from the date of committal of the said offence against the law.
2. The time effect of punishments shall last for three years starting from the date of announcement of the decision on administering the said punishments.

Article 59

Detention and Accessory Punishments

In the procedures of initiating an offence against the law, orders shall be issued to detain the articles and products used in the committal of the said offence against the law, as well as administering the following accessory punishments:

a) Revocation or termination of the authorization of engagement in relevant businesses; and

b) Prohibition of engagement in relevant occupations or businesses for a period of no more than three years.

Article 60

Abuse of Authorization

1. Those who use authorizations granted in accordance with this Act for purposes other than those stipulated in the said authorizations shall be fined at between 10,000 and 200,000 Macao dollars.
2. Those using the substances or preparations listed in the tables referred to in Article 1 for purposes other than those stipulated in authorizations or violating the special terms set in decisions on such authorizations shall be fined at the same amount mentioned in the preceding clause.

Article 61

Unauthorized Activities

Those carrying on relevant activities after nullification, termination or revocation of an authorization shall be fined at between 10,000 and 50,000 Macao dollars.

Article 62

False or Erroneous Information

1. Those who already know that certain information is false or erroneous but still provide such information for the obtainment of authorizations shall be fined at between 5,000 and 50,000 Macao dollars.
2. Those who do so due to negligence shall also be punished, and the maximum and minimum fines to be imposed, as prescribed above, shall be halved.

Article 63

Prohibition of Export

1. Those exporting substances or preparations in violation of the stipulations in 1, 2 or 3, Article 31, shall be fined at between 10,000 and 50,000 Macao dollars.
2. The same amount of fines shall be imposed upon those violating the stipulations in 3, Article 34.

Article 64

Lack of Orders

1. Those who deliver the substances or preparations listed in tables 1-4 without the force of orders referred to 1, Article 23 or deliver these substances or preparations to parties other than those stipulated in Article 25 shall be fined at between 5,000 and 50,000 Macao dollars. This need not apply, however, to the substances listed in Table 2 – A.
2. Those who mail or deliver samples of the preparations listed in Table 4 without the authorization referred to in Clause 3, Article 23 shall be fined at between 2,500 and 10,000 Macao dollars.
3. The same amount of fines as specified in the preceding clause, plus an extra one third of this amount, shall be imposed upon those who mail or deliver samples of the substances or preparations listed in Table 1, Table 2 or Table 3.

Article 65

Books, Documents and Registries

1. Those who fail to fill the books, documents or registries as required in this Act or fill them with false or erroneous information shall be fined at between 10,000 and 100,000 Macao dollars.
2. Those who fail to keep the books, documents or registries referred to in the preceding clause shall be fined at between 5,000 and 15,000 Macao dollars.
3. Those who fail to fill the books, documents or registries referred to in Clause 1 of this article according to regulations shall be fined at between 2,500 and 10,000 Macao dollars.

Article 66

Security and Obligation to Provide Information

1. Those who keep the substances and preparations listed in tables 1-4 or assume the responsibility over their safety shall be fined at between 10,000 and 50,000 Macao dollars if the said substances or preparations are subtracted or lost due to their negligence or failure to take measures as required by SSM.
2. Those who fail to notify the police authorities according to stipulations in Clause 1,3 and 4, Article 25, or notify the police authorities only after expiration of the set time limit shall be fined at between 1,500 and 15,000 Macao dollars.

Article 67

Violation of Provisions on Prohibition of Delivery to Psychotics or Minors

1. Those who violate stipulations in Clause 1, Article 41 shall be fined at between 20,000 and 50,000 Macao dollars.
2. Those who fail to bind themselves by the obligations stipulated in Clause 3, Article 41 shall be fined at between 2,000 and 10,000 Macao dollars.

Article 68

Failure in Submission of Documents or Information for the Purpose of Exercising Control

Those who violate the stipulations in Clause 3, Article 26, Clause 2, Article 35, Clause 3, Article 40, and Clause 2, Article 42 on the submission of documents or information for the purpose of exercising control or fail to provide information as required by the authorities according to stipulations in Article 4 shall be fined at between 3,000 and 15,000 Macao dollars.

Article 69

Publicity

Those who publicize the substances or preparations listed in the tables referred to in Article 1 in violation of this Act shall be fined at between 10,000 and 100,000 Macao dollars.

CHAPTER IV

Final and Transitional Provisions

Article 70

Time Limit for Execution of New Measures

The measures on registries, as stipulated in this Act, shall be put into execution within three months after this Act comes into force.

Article 71

Import, Export and Marketing of Medicinal Products

Entities licensed to import, export or wholesale medicinal products shall apply for relevant authorizations within three months after this Act comes into force if they hope to engage in the import, export, wholesale, or distribution of the substances or preparations listed in the tables referred to in Article 1.

Article 72

Inventory of Stocks

1. Laboratories, businesses specializing in the export or wholesale of medicinal products, pharmacies, and other entities that possess the substances or preparations listed in the tables referred to in Article 1 or that possess the samples of these substances or preparations shall submit to SSM, within 30 days after this Act comes into force, inventories of their stocks containing the following information:

   a) The commercial, common, or internationally used names of the drugs;

   b) Form and content;

   c) Types of packaging and quantity of each pack;

   d) Total number of packs; and

   e) Batch numbers and dates of expiry.

2. Physicians who possess the said substances or preparations or who possess merely samples of these substances or preparations at the time this Act comes into force shall also hand over the said substances, preparations or samples to SSM within the time limit set in the preceding clause, and identify them according to stipulations in the preceding clause.

Article 73

Provisions on Nullification

The stipulations in Clause 5, Article 10 of Decree No 30/95/M of 10th, July shall be nullified.

Article 74

Entry into Force

This Act shall come into force on the first day of the month following the month of its promulgation.

Examined and approved on 15th, July, 1999, this Act is hereby promulgated by the decree of Vasco Rocha Vieira, the Governor.