

## PHARMACEUTICAL AFFAIRS ACT

Wholly	Amended by	Act No.	8365,	Apr.	11,	2007
Wholly	Amended by	Act No.	8558,	Jul.	27,	2007
		Act No.	8643,	Oct.	17,	2007
		Act No.	8723,	Dec.	21,	2007
		Act No.	8728,	Dec.	21,	2007
		Act No.	8852,	Feb.	29,	2008
		Act No.	9123,	Jun.	13,	2008
		Act No.	9819,	Nov.	2,	2009
		Act No.	9847,	Dec.	29,	2009
		Act No.	9932,	Jan.	18,	2010
		Act No.	10324,	May	27,	2010

### CHAPTER I GENERAL PROVISIONS

#### Article 1 (Purpose)

The purpose of this Act is to prescribe the matters that are needed to deal with matters regarding pharmaceutical affairs smoothly, thereby to contribute to the improvement of national public health.

#### Article 2 (Definitions)

The definitions of terms used in this Act shall be as follows: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9847, Dec. 29, 2009; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011>

1. The term “pharmaceutical affairs” means the manufacture, dispensing, evaluation, safekeeping, importation and sale (including presentation; hereinafter the same shall apply) of medicinal products and quasi-drugs, and other matters related to pharmaceutical technology;
2. The term “pharmacist” means a person who takes charge of the matters concerning pharmaceutical affairs (including those concerning herbal medicinal products), other than those concerning herbal medicines, and the term “oriental pharmacist” means a person who takes charge of the matters concerning pharmaceutical affairs related to herbal medicines and herbal medicinal products, and both of them shall be licensed by the Minister of Health and Welfare;

3. The term “pharmacy” means a place where a pharmacist or an oriental pharmacist dispenses drugs (including the dispensing of pharmacy medication) for the purpose of presentation (including the place needed for distribution business in cases where the founder of the pharmacy engages in drug distribution business at the same time); However, the dispensaries of medical institutions shall be excluded;
4. The term “drug” means a product falling under any of the following subparagraphs:
  - (a) Those, other than quasi-drugs, among products listed in the Korean Pharmacopoeia;
  - (b) Products used for the purposes of diagnosis, medical care, alleviation, treatment or prevention of diseases of human beings or animals, excluding appliances, machinery and equipment;
  - (c) Products, other than appliances, machinery or equipment, used for the purpose of exerting pharmacological effects upon the structure or functions of human beings or animals;
5. The term “herbal medicine” means raw materials picked from animals, plants or minerals, which have been dried, cut or carefully prepared without changing the original forms in most cases;
6. The term “herbal medicinal product” means a drug made by mixing herbal medicines according to the principle of oriental medicine;
7. The term “quasi-drug” means a product designated by the Minister of Health and Welfare, which falls under any of the followings (excluding products which shall be used for the purposes pursuant to subparagraph 4 (b) or (c)):
  - (a) Fibers, rubber products or similar products used for the purpose of treating, alleviating, or preventing human or animal diseases;
  - (b) Non-appliance, non-machinery or similar products which have insignificant influences on or do not directly act upon human bodies;
  - (c) Preparations used for sterilization, insecticide and purposes similar thereto in order to prevent communicable diseases;
8. The term “new drug” means a drug of new materials, the chemical structure or the construction of substance of which is wholly new, or a drug of composite medication containing new materials as effective ingredients, which is designated

- by the Commissioner of the Korea Food and Drug Administration;
9. The term “over-the-counter drug” means a drug that falls under any of the followings and conforms to the standards prescribed and announced by the Minister of Health and Welfare:
- (a) A drug, the misuse or the abuse of which is of little concern, and the safety and efficacy of which may be expected even when used without a prescription by a doctor or a dentist;
  - (b) A drug that may be used to cure a disease without a doctor’s or dentist’s professional knowledge;
  - (c) A drug that has a relatively small side effect on human bodies in light of its dosage form and pharmacological action;
10. The term “prescription drug” means a drug that is not an over-the-counter drug;
11. The term “dispensing of drug” means preparing drugs to be used for the purposes of treatment, prevention, etc. of a certain disease for a specific individual in accordance with the specific directions by mixing two or more drugs or by dividing one kind of drug into certain dosages according to a specific prescription;
12. The term “medication consulting” means those falling under any of the followings:
- (a) Providing information on the name, directions for use and dosage, efficacy and effect, storage methods, adverse drug reactions and interactions, etc. of drugs;
  - (b) Assisting consumers in choosing necessary drugs without passing diagnostic judgment when selling over-the-counter drugs;
13. The term “safety container or package” means a container or package designed and devised to make it difficult for children under the age of five to open;
14. The term “contract manufacture” means a pharmaceutical manufacturing business without possessing manufacturing facilities of medicinal products by entrusting the manufacture of drugs, which have obtained manufacturing and marketing approval from the Commissioner of the Korea Food and Drug Administration, to a pharmaceutical manufacturer.
15. The term “clinical trial” means a test which checks pharmacokinetics, pharmacodynamics, medical actions and clinical efficacy of the relevant

- drugs against humans and investigate allergic reactions, in order to prove the safety and effectiveness of drugs, etc.:
16. The term “non-clinical trial” means a test conducted by using animals, plants or microorganism, and physical or chemical medium, or the composite thereof in the same condition as that of a laboratory, so as to obtain various data on the nature or safety of test materials which influence the health of humans:
17. The term “biological equivalence examination” means a test conducted on a living body aimed at proving biological equivalence, which shows that the bioavailability of two medicines containing the same major ingredients is statistically equivalent.

## CHAPTER II PHARMACISTS AND ORIENTAL PHARMACISTS

### SECTION 1 Qualification and Licenses

#### Article 3 (Qualification and Licenses of Pharmacists)

- (1) Any person who desires to become a pharmacist shall obtain a license from the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) A license of a pharmacist under paragraph (1) shall be granted to a person falling under any of the following subparagraphs: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
1. A person who has graduated from a college of pharmacy and received a bachelor’s degree in pharmacy, and passed the national examination for pharmacists;
  2. A person who has graduated from a foreign college of pharmacy, accredited by the Minister of Health and Welfare, obtained a foreign license of a pharmacist, and passed the national examination for pharmacists.
- (3) Any person who has not obtained a pharmacist license shall be prohibited from using the title of “pharmacist.”

## Article 4 (Qualification and Licenses of Oriental Pharmacists)

(1) Any person who desires to become an oriental pharmacist shall obtain a license from the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(2) A license of an oriental pharmacist under paragraph (1) shall be granted to a person who has majored in oriental pharmacy in a college, received a bachelor's degree in oriental pharmacy, and passed the national examination for oriental pharmacist.

(3) Any person who has not obtained a license of an oriental pharmacist shall be prohibited from using the title of "oriental pharmacist."

## Article 5 (Disqualification)

No license of a pharmacist or oriental pharmacist shall be granted to a person falling under any of the following subparagraphs: <Amended by Act No. 8643, Oct. 17, 2007>

1. A mental patient under subparagraph 1 of Article 3 of the Mental Health Act: However, this shall not apply to a person who is recognized by a medical specialist to be suitable for taking charge of pharmaceutical affairs;
2. An incompetent or quasi-incompetent person;
3. A narcotic addict or a person intoxicated with any other harmful substance;
4. A person who has been sentenced to imprisonment without prison labor or heavier penalty on charges of violating the Pharmaceutical Affairs Act, the Act on the Control of Narcotics, etc., the Act on Special Measures for the Control of Public Health Crimes, the Medical Service Act, Article 347 of the Criminal Act (limited to cases of deceiving patients or an institution or organization paying drug expenses by demanding drug expenses in a fraudulent manner; hereinafter the same shall apply) and other Acts and subordinate statutes related to pharmaceutical affairs, and for whom the sentence has yet to be terminated or exemption from its execution has yet to be made definite;
5. A person who has been subject to a disposition of cancellation of his/her license by committing the crimes under Article 347 of the Criminal Act and for whom three years have not elapsed, or who has been subject to a disposition of cancellation

of his/her license for violating Acts and subordinate statutes relating to pharmaceutical affairs and for whom two years have not elapsed.

## Article 6 (Issuance and Registration of Licenses)

(1) When the Minister of Health and Welfare issues a pharmacist's or oriental pharmacist's license, he/she shall register matters relating to the license in the relevant registry and issue the license concerned. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(2) If a license referred to in paragraph (1) has been lost or damaged, or the matters stated therein have been changed, a new license may be issued in lieu thereof.

(3) No license shall be lent to any other person.

(4) Matters necessary for registration of a pharmacist's or oriental pharmacist's license and issuance thereof shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

## Article 7 (Reporting by Pharmacists or Oriental Pharmacists)

Each pharmacist or oriental pharmacist shall report matters prescribed by Ordinance of the Ministry of Health and Welfare to the Minister of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

## Article 8 (National Examinations for Pharmacists or Oriental Pharmacists)

(1) National examinations for pharmacists or oriental pharmacists shall be conducted by the Minister of Health and Welfare at least once a year. <Amended by Act No. 88562, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(2) The Minister of Health and Welfare may commission relevant specialized institutions to administer national examinations for pharmacists or oriental pharmacists ~~herb~~ pharmacists referred to in paragraph (1), as prescribed by Presidential Decree. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(3) The Minister of Health and Welfare may, when he/she commissions specialized institutions to administer national examinations under paragraph (2), subsidize necessary expenses. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(4) Matters necessary for national examinations for pharmacists or oriental pharmacists shall be prescribed by Presidential Decree.

## Article 9 (Restrictions on Application for Examinations)

No person falling under subparagraphs 1 through 3 of Article 5 shall apply for

any national examination for pharmacists or oriental pharmacists.

Article 10 (Cheating of Examinees)

(1) Any person who has cheated in a national examination for pharmacists or oriental pharmacists shall be suspended from taking the examination, and where the fact of cheating is found after a candidate has passed the examination, the pass shall be nullified.

(2) The Minister of Health and Welfare may prohibit persons falling under paragraph (1) from applying for a national examination for pharmacists or oriental pharmacists for two years. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

## SECTION 2 Pharmaceutical Association and Oriental Pharmacy Association

Article 11 (Pharmaceutical Association)

(1) Pharmacists shall establish the Korean Pharmaceutical Association (hereinafter referred to as the “Pharmaceutical Association”), as prescribed by Presidential Decree, to research pharmaceutical affairs, establish pharmacists’ ethics, promote pharmacists’ rights and interests and elevate their quality.

(2) The Pharmaceutical Association shall be a juristic person.

(3) When the Pharmaceutical Association is established, pharmacists shall duly become its members.

(4) The provisions of the Civil Act relating to corporate juridical persons, in addition to those provided for in this Act, shall apply *mutatis mutandis* to the Pharmaceutical Association.

Article 12 (Oriental Pharmacy Association)

(1) Oriental pharmacists shall establish the Association of Korea Oriental Pharmacy (hereinafter referred to as the “Oriental Pharmacy Association”), as prescribed by Presidential Decree to research pharmaceutical affairs in connection with herbal medicine and herbal medicinal products, establish oriental pharmacists’s ethics, promote oriental pharmacists’ rights and interests and improve their qualifications.

(2) The Oriental Pharmacy Association shall be a juristic person.

(3) When the Oriental Pharmacy Association is established, oriental pharmacists shall duly become its members.

(4) The provisions of the Civil Act concerning corporate juristic persons, in addition to those provided for in this Act, shall apply *mutatis mutandis* to the Oriental Pharmacy Association.

Article 13 (Authorization, etc.)

(1) When the Pharmaceutical Association or Oriental Pharmacy Association is established, the articles of association and other necessary documents shall be submitted to the Minister of Health and Welfare and authorization from him/her shall be obtained, as prescribed by Presidential Decree. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(2) Matters to be stated in the articles of association by the Pharmaceutical Association or by the Oriental Pharmacy Association shall be prescribed by Presidential Decree.

(3) If the Pharmaceutical Association or Oriental Pharmacy Association intends to amend its articles of association, it shall obtain authorization therefor from the Minister of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 14 (Chapters, etc. of Pharmaceutical Association and Oriental Pharmacy Association)

(1) The Pharmaceutical Association or Oriental Pharmacy Association shall establish its chapters in a Special Metropolitan City, Metropolitan City, *Do* and Special Self-Governing Province (hereinafter referred to as “City/*Do*”), and may establish branches in the *Gu* of a Special Metropolitan City or Metropolitan City, *Si* (referring to an administrative city, in cases of a Special Self-Governing Province; hereinafter the same shall apply) or *Gun*.

(2) When the Pharmaceutical Association or Oriental Pharmacy Association has established its chapters and branches, it shall promptly file a report thereon with the Special Metropolitan City Mayor, Metropolitan City Mayor, *Do* Governor or Governor of a Special Self-Governing Province (hereinafter referred to as “Mayor/*Do* Governor”).

Article 15 (Training and Education)

(1) The Minister of Health and Welfare may order pharmacists and oriental pharmacists to undergo training and education for the improvement of their qualifications. <Amended

by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(2) Necessary matters concerning training and education under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 16 (Duties of Cooperation and Entrustment)

(1) The Pharmaceutical Association or Oriental Pharmacy Association shall comply with a request for cooperation from the Minister of Health and Welfare concerning projects for the improvement of national public health, pharmaceutical affairs, and pharmacists' or oriental pharmacists' ethics. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(2) The Minister of Health and Welfare may entrust some of duties concerning pharmaceutical affairs and pharmacists' or oriental pharmacists' ethics to the Pharmaceutical Association or Oriental Pharmacy Association, as prescribed by Presidential Decree. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 17 (Subsidization of Expenses)

When the Minister of Health and Welfare deems that the programs of the Pharmaceutical Association or Oriental Pharmacy Association are necessary for the improvement of national public health, or when he/she has ordered or entrusted such Association to conduct training, investigation and research on pharmacists or oriental pharmacists, he/she may fully or partially subsidize necessary expenses. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

### CHAPTER III PHARMACEUTICAL AFFAIRS COUNCIL

Article 18 (Central Pharmaceutical Affairs Council)

(1) The Central Pharmaceutical Affairs Council shall be established under the control of the Ministry of Health and Welfare in order to provide the Minister of Health and Welfare and the Commissioner of the Korea Food and Drug Administration with advices when requested. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(2) Matters necessary for the organization and operation of the Central Pharmaceutical

Affairs Council and other necessary matters, shall be prescribed by Presidential Decree.

Article 19 Deleted. <by Act No. 10512, Mar. 30, 2011>

### CHAPTER IV PHARMACIES AND DISPENSING OF DRUGS

#### SECTION 1 Pharmacies

Article 20 (Registration for Establishment of Pharmacies)

(1) No person, other than a pharmacist or oriental pharmacist, shall establish a pharmacy.

(2) Any person intending to establish a pharmacy shall make a registration for establishment with the head of a *Si/Gun/Gu* (referring to the head of an autonomous *Gu*; hereinafter the same shall apply), as prescribed by Ordinance of the Ministry of Health and Welfare. The same shall apply to revisions to registered matters. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(3) Any person wishing to make a registration under paragraph (2) shall be equipped with necessary facilities in conformity with the standards of facilities prescribed by Presidential Decree.

(4) A Mayor/*Do* Governor may set the standards of registration for establishing a pharmacy, respectively by the regulations of the relevant City/*Do* in conformity with the standards prescribed by Presidential Decree.

(5) In cases falling under any of the following subparagraphs, no application for the registration for establishment of a pharmacy shall be accepted:

1. Where a person whose registration for establishment of a pharmacy has been cancelled pursuant to Article 76 intends to make a registration within six months from the date of such cancellation;
2. Where a pharmacy is to be established in a place which is located within facilities or premises of a medical institution;
3. Where a pharmacy is established by dividing, altering or repairing part of facilities or sites of a medical institution;

4. Where a pathway, such as an exclusive corridor, a flight of stairs, an elevator or a footbridge, is in place or to be constructed between a pharmacy and a medical institution.

Article 21 (Duties to Manage Pharmacies)

- (1) A pharmacist or oriental pharmacist may establish only one pharmacy.
- (2) Any pharmacy founder shall manage the pharmacy in person: However, where a pharmacy founder is unable to run the pharmacy, he/she shall designate a pharmacist or an oriental pharmacist to run such pharmacy on behalf of him/her.
- (3) Every pharmacist or oriental pharmacist who manages a pharmacy shall observe the following matters necessary to manage such pharmacy: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
1. He/she shall manage his/her pharmacy and drugs to ensure that they do not inflict harm to health and sanitation and they maintain the efficacy;
  2. He/she shall thoroughly oversee his/her employees in order to prevent any incident related to health and sanitation;
  3. He/she shall keep any goods feared to incur any sanitary danger off from his/her pharmacy;
  4. In the event that any adverse reaction, etc. occurs in connection with the use of drugs, etc., he/she shall file a report thereon, as prescribed by the Commissioner of the Korea Food and Drug Administration, and take necessary safety steps;
  5. He/she shall observe other matters corresponding to the provisions of subparagraphs 1 through 4 and recognized by Ordinance of the Ministry of Health and Welfare as necessary to manage the facilities and drugs of pharmacies in a manner not inflicting harm to health and sanitation.

Article 22 (Reporting on Discontinuation of Business, etc.)

Where a pharmacy founder discontinues the business of running the pharmacy, or suspends such business or resumes the suspended business, he/she shall file a report thereon with the head of a *Si/Gun/Gu* having jurisdiction over his/her business within seven days from the date of discontinuation, suspension or resumption, as prescribed by Ordinance of the Ministry of Health and Welfare: However, the same shall not apply in cases where a period for business suspension is less than

one month. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

## SECTION 2 Dispensing of Drugs

Article 23 (Dispensing of Drugs)

- (1) No person, other than pharmacists or oriental pharmacists, may dispense drugs, and pharmacists or oriental pharmacists shall dispense drugs within the limit of the license, respectively: However, students who major in pharmacy at college may dispense drugs within the limits prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) When a pharmacist or oriental pharmacist is to dispense drugs, he/she shall do so at a pharmacy or a dispensary of a medical institution (including a dispensary installed in the Korea Orphan Drug Center pursuant to the latter part of Article 92 (1) 2): However, this shall not apply in cases where he/she has obtained approval from the head of a *Si/Gun/Gu*.
- (3) Any doctor or dentist shall be entitled to prescribe prescription drugs and over-the-counter drugs and any pharmacist shall be entitled to dispense prescription drugs and over-the-counter drugs according to the prescriptions issued by doctors or dentists: However, a pharmacist may dispense drugs without prescriptions issued by a doctor or dentist in cases falling under any of the following subparagraphs: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9847, Dec. 29, 2009; Act No. 9932, Jan. 18, 2010>*
1. Where he/she dispenses drugs in an area where no medical institution exists;
  2. Where he/she dispenses drugs for the purpose of disaster relief after a natural disaster renders medical institutions virtually nonexistent;
  3. Where he/she sells oral vaccines to prevent spread of a communicable disease after the Minister of Health and Welfare recognizes that such communicable disease has broken out or is feared to break out widely;
  4. Where he/she dispenses drugs for social service activities.
- (4) Notwithstanding the provisions of paragraph (1), a doctor or dentist may directly dispense drugs, in any of the following cases: *<Amended by Act Nos. 8723 & 8728, Dec. 21, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9819, Nov. 2, 2008; Act No. 9847, Dec. 29, 2009;>*

*Act No. 9932, Jan. 18, 2010*>

1. Where he/she dispenses drugs in an area where no pharmacy exists;
2. Where he/she dispenses drugs for the purpose of disaster relief after a natural disaster renders pharmacies virtually nonexistent;
3. Where he/she dispenses drugs for an emergency patient or a mental patient suffering from schizophrenia or a manic-depressive insanity, etc. who is feared to harm himself/herself and others;
4. Where he/she dispenses drugs for an in-patient, a patient suffering from a Type I communicable disease under the Communicable Disease Control and Prevention Act or a person admitted to a social welfare facility under the Social Welfare Services Act (in cases where the person does not board and lodge in such facility, it shall be limited only to the dispensing of drugs during a period for which he/she utilizes such facility);
5. Where he/she gives injections;
6. Where he/she makes dosages of vaccines to prevent communicable diseases, drugs for medical examinations and other drugs, etc. prescribed by Ordinance of the Ministry of Health and Welfare;
7. Where he/she, while serving in a public health center or its branch office under the Regional Public Health Act, dispenses drugs for patients as one of his/her duties (excluding treatment of visiting residents within the jurisdiction of a public health center and a public health branch office designated by the Minister of Health and Welfare);
8. Where he/she prepares drugs for veterans suffering from wound-rating I through III under the Act on the Honorable Treatment and Support of Persons, etc. of Distinguished Services to the State and its Enforcement Decree, persons corresponding to disability-rating I through IV, from among persons wounded in the 5.18 Democratization movement under the Act on the Honorable Treatment of Persons of Distinguished Services to the 5.18 Democratization Movement, highly handicapped persons under the Act on Assistance, etc. to Patients from Actual or Potential Aftereffects of Defoliants and its Enforcement Decree, grades I and II handicapped persons under Acts and subordinate statutes related

- to the welfare of handicapped persons, handicapped persons equivalent thereto, and patients suffering from Parkinson's disease or Hansen's disease;
9. Where he/she dispenses drugs for the treatment of persons having undergone the surgery of internal organ transplant and the treatment of patients suffering from AIDS;
  10. Where he/she dispenses drugs for military servicemen in the course of discharging military duty, combat police officers, guards of any correctional institution and other persons who are held in correction facilities under the Administration and Treatment of Correctional Institution Inmates Act and the Administration and Treatment of Military Inmates Act, juvenile protection facilities under the Treatment of Protected Juveniles, etc. Act and foreigner protection facilities under the Immigration Control Act;
  11. Where he/she makes dosages of drugs for the treatment of tuberculosis under the Tuberculosis Prevention Act (limited to public health centers, public health branches and affiliated hospitals of the Korean National Tuberculosis Association);
  12. Where he/she dispenses drugs for social service activities;
  13. Where prescriptions are prohibited from being disclosed for the sake of the preservation of information related to the national security;
  14. Other cases prescribed by Presidential Decree.
- (5) The scope of the area where no medical institution or pharmacy exists, as referred to in paragraph (3) 1 or (4) 1, shall be determined by the Minister of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010 >*
- (6) When an oriental pharmacist dispenses any herbal medicine, he/she shall comply with the prescription of an oriental pharmacist: However, in cases where he/she dispenses it according to the category of herbal medicine prescription or dispensing method determined by the Minister of Health and Welfare, he/she may dispense it without prescription of an oriental pharmacist. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010 >*
- (7) Any pharmacist dispensing drugs at a dispensary of a medical institution shall be prohibited from dispensing any drug for a patient to whom a prescription is

issued under Article 18 of the Medical Service Act.

Article 24 (Duties and Matters to be Observed)

(1) No pharmacist or oriental pharmacist dispensing drugs at a pharmacy, shall refuse any request for dispensing drugs, without justifiable grounds.

(2) Any pharmacy founder (including persons working for the relevant pharmacy; hereafter the same shall apply in this Article) and any medical institution founder (including persons working for the relevant medical institution; hereafter the same shall apply in this Article) shall be prohibited from engaging in any of the following collusive acts:

1. The act, performed by any pharmacy founder, of wholly or partially exempting any person carrying a medical prescription written by a specific medical institution from drug expenses;
2. The act, performed by any pharmacy founder, of offering money, articles, favors, labor, entertainment and other economic interest in return for medical prescriptions arranged by a specific medical institution founder in favor of him/her;
3. The act, performed by any medical institution founder, of directing or inducing any person carrying its medical prescription to get such medical prescription dispensed at a specific pharmacy (excluding the act of introducing in full the names, locations, etc. of pharmacies in the relevant area at the request of any patient);
4. The act, performed by any doctor or dentist, of repeatedly prescribing other drugs that are identical in composition to the drugs that are included in the list of drugs for prescription provided by the branches of the Medical Association or the branches of the Dental Association to the branches of the Pharmaceutical Association under Article 25 (2) (the same shall apply to any pharmacist who repeatedly dispenses the relevant drugs according to the relevant medical prescription);
5. Any other act similar to that referred to in subparagraphs 1 through 4 and prescribed by Presidential Decree as having the potential of collusion.

(3) Any pharmacist or oriental pharmacist working at a dispensary of a medical institution under Article 23 (2) shall, when he/she dispenses drugs, observe matters

prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(4) Every pharmacist shall, when he/she dispenses drugs for any patient, give the medication consulting to the relevant patient.

(5) The Minister of Health and Welfare may take necessary steps to get pharmacists to faithfully offer patients the medication consulting provided for in paragraph (4) through the dispensing of a proper number of medical prescriptions. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 25 (Drawing Up List of Prescription Drugs)

(1) Any medical institution founder shall submit a list of drugs that the relevant medical institution intends to prescribe to the branch of the Medical Association or the branch of the Dental Association (hereinafter referred to as “branch of the Medical Association, etc.”), which has been established pursuant to Article 28 (5) of the Medical Service Act, of the *Si/Gun/Gu* where such medical institution is located.

(2) The branch of the Medical Association, etc. shall provide the branch of the Pharmaceutical Association of the relevant *Si/Gun/Gu* with a regional list of prescription drugs which has been obtained by adjusting the list of prescription drugs of each medical institution pursuant to paragraph (1) to a reasonable number of articles and a list of prescription drugs of each medical institution which has been obtained by adjusting within the extent of the drugs in the regional list of prescription drugs.

(3) The branch of the Pharmaceutical Association shall, upon receiving the regional list of prescription drugs and the list of prescription drugs of each medical institution from the branch of the Medical Association, etc. under paragraph (2), furnish pharmacy founders in the relevant area with such lists and have them secure relevant drugs.

(4) Where any pharmacy founder finds it difficult to secure drugs according to the list of prescription drugs referred to in paragraph (2) and that it becomes necessary to adjust the number of articles, the branch of the Medical Association, etc. and the branch of the Pharmaceutical Association may adjust it through consultations. The same shall apply in cases where the numbers of articles are added or altered.

(5) The branch of the Medical Association, etc. shall, if it intends to alter or add



the list of prescription drugs referred to in paragraph (2), file a notice to that effect with the branch of the Pharmaceutical Association 30 days in advance.

Article 26 (Modification and Revision of Prescriptions)

(1) No pharmacist or oriental pharmacist shall dispense drugs by modifying or revising prescriptions without the consent of the doctor, dentist, oriental doctor or veterinarian who has made the prescriptions.

(2) In cases where a name, quantity, directions, dose, etc. of a drug written in a prescription is suspected to fall under any of the following subparagraphs, a pharmacist or oriental pharmacist shall not dispense drugs unless he/she has confirmed any suspect points by telephone and fax or by telephone and e-mail with the doctor, dentist, oriental doctor or veterinarian who has issued the prescription: <Amended by Act No. 8558, Jul. 27, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

1. In cases where a drug, for which product approval or report has been revoked by the Commissioner of the Korea Food and Drug Administration because of any defect in terms of safety and efficacy, is written in the prescription;
2. In cases where it is unable to confirm a product name of a drug or names of ingredients thereof;
3. In cases where a drug, which has been announced by the Minister of Health and Welfare to be banned from use in combination or use for a specific age bracket pursuant to the basis of medical treatment benefit prescribed by Ordinance of the Ministry of Health and Welfare pursuant to Article 39 (2) of the National Health Insurance Act, is written in the prescription.

(3) Detailed matters, such as the method of and procedures for revising and modifying prescriptions under paragraph (1), shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 27 (Dispensing Substitute Drugs)

(1) When a pharmacist intends to dispense a drug by substituting the drug in a prescription slip issued by a doctor or dentist with a drug of the same ingredients, content and dosage form, he/she shall obtain prior consent of the doctor or dentist who has issued the prescription slip.

(2) Notwithstanding the provisions of paragraph (1), a pharmacist may dispense

a substitute drug without obtaining prior consent of the doctor or dentist who has issued the prescription slip where it falls under any of the following subparagraphs:

1. Where the pharmacist dispenses a substitute drug which has been recognized by the Commissioner of the Korea Food and Drug Administration as having biological equivalence (including drugs that prove their biological equivalence through a medical experiment using no living body because of the needlessness to conduct a medical experiment using a living body or of the impossibility to do so): However, in case where the doctor or dentist has indicated in the prescription slip that the dispensing a substitute drug is not permissible, and has written in detail the clinical reasons, etc. therefor, such article shall be excluded;
2. Where the pharmacist dispenses a substitute drug with the same prescription dosage, which has been manufactured by the same drug manufacturer who also manufactures the drug stated in the prescription slip, and which is different in content but is of the same ingredients and dosage form: However, dispensing such substitute drug shall be limited only to cases where a substitute over-the-counter drug is prepared in place of an over-the-counter drug and a substitute prescription drug is prepared in place of a prescription drug;
3. Where there is an unavoidable reason for which it is difficult to obtain prior consent of the doctor or dentist who has issued the prescription slip in cases where the drug stated in the prescription slip, which has been issued by a medical institution located in a region, other than a *Si/Gun/Gu* in which the pharmacy is located, is not included in the regional list of prescription drugs, and the dispensing is substituted by a drug of the same ingredients, content and dosage form as the drug stated in the prescription slip in the regional list of prescription drugs of the pharmacy concerned.
- (3) Every pharmacist shall, if he/she dispenses a substitute drug instead of the drug stated in a prescription slip under paragraph (1) or (2), notify the person carrying such prescription slip of the detail of such substitute drug that has been dispensed.
- (4) Every pharmacist shall, if he/she dispenses a substitute drug instead of the

drug entered in a prescription slip under paragraph (2), notify the doctor or dentist who has issued such prescription slip of the details of such substitute drug that has been dispensed within one day from the date of dispensing (within three days if extenuating circumstances exist): However, the same shall not apply in cases where the pharmacist dispenses such substitute drug after obtaining prior consent of the doctor or dentist who has issued the prescription slip thereof.

(5) Where any pharmacist dispenses a substitute drug instead of the drug entered in a prescription slip without prior consent of the doctor or dentist who has issued such prescription slip, such doctor or dentist shall not be held responsible for any drug accident caused by such substitute drug.

(6) Necessary matters concerning methods of and procedures for obtaining consent and providing notice, etc. under paragraphs (1) and (4) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

#### Article 28 (Indication and Recording of Drugs Dispensed)

(1) A pharmacist or oriental pharmacist shall indicate the relevant patient's name, directions, and dose mentioned in the pertinent prescription slip and other matters prescribed by Ordinance of the Ministry of Health and Welfare on the containers or packages of drugs dispensed for sale. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) When a pharmacist or oriental pharmacist has dispensed drugs, he/she shall indicate in the prescription slip, the date of dispensing and other matters prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

#### Article 29 (Preservation of Prescriptions)

Every pharmacist or oriental pharmacist shall preserve prescriptions by which he/she has dispensed drugs at his/her pharmacy, for two years from the date of dispensing

#### Article 30 (Preparation Records)

(1) Every pharmacist shall, whenever he/she dispenses drugs (including cases where drugs are dispensed without prescription under subparagraphs of Article 23 (3) and the proviso to the main part of Article 23 (3); hereinafter the same shall apply in this Article) at his/her pharmacy, enter the personal information of a patient,

the date of dispensing, the names of prescribed drugs and the days of taking drugs, details of dispensing, details of medication consulting and other matters prescribed by Ordinance of the Ministry of Health and Welfare in his/her dispensing records (including electronic records) and preserve such dispensing records for not less than five years. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) Where any patient, his/her spouse, his/her lineal ascendant or descendant, or his/her spouse's lineal ascendant (an agent designated by such patient in cases where his/her spouse, his/her lineal ascendant or descendant and his/her spouse's lineal ascendant are all nonexistent) requests a perusal of the dispensing records preserved under paragraph (1), an issuance of a copy of such dispensing records and confirmation of details of such dispensing records, etc., a pharmacist shall comply with such request.

## CHAPTER V MANUFACTURE, IMPORTATION, ETC. OF DRUGS, ETC.

### SECTION 1 Manufacturing Business of Drugs, etc.

#### Article 31 (Licensing of Manufacturing Business, etc.)

(1) A person who intends to engage in business of manufacturing drugs shall obtain a license from the Commissioner of the Korea Food and Drug Administration, as prescribed by Ordinance of the Ministry of Health and Welfare, after being equipped with necessary facilities pursuant to the standards for facilities prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) In cases where a manufacturer under paragraph (1) intends to sell drugs manufactured (including cases of entrusting another manufacturer with manufacture), he/she shall obtain product approval of manufacture and sale (hereinafter referred to as "product approval") from the Commissioner of the Korea Food and Drug Administration or submit a product report of manufacture and sale (hereinafter referred to as "product report"), as prescribed by Ordinance of the Ministry of

Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008>

(3) In cases where a person, other than a manufacturer under paragraph (1), intends to entrust a manufacturer with manufacture of a drug which has been put to clinical trials after having obtained approval for a plan of clinical trials pursuant to Article 34 (1) and sell it, he/she shall submit a report on contract manufacture to the Commissioner of the Korea Food and Drug Administration and obtain product approval per each product, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(4) A person who intends to engage in business of manufacturing quasi-drugs shall submit a report on manufacture business to the Commissioner of the Korea Food and Drug Administration after being equipped with necessary facilities pursuant to the standards for facilities prescribed by Presidential Decree, and obtain product approval per each product or submit a product report.

(5) A person who has obtained product approval or has submitted a product report pursuant to paragraphs (2) and (3) (hereinafter referred to as “person who has obtained product approval”) may establish a business office, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(6) Notwithstanding the provisions of paragraphs (1) through (4), a license for manufacture, product approval or product report of drugs or quasi-drugs, which have been prescribed by Ordinance of the Ministry of Health and Welfare, including drugs for clinical trials under Article 34 may be omitted. <Newly Inserted by Act No. 10512, Mar. 30, 2011>

(7) Notwithstanding the provisions of paragraphs (2) through (4), the combination or mixed composition of drugs, etc. and medical appliances, the main function of which is that of medical appliances, which have obtained a license or made a report under the Medical Appliances Act shall be deemed to have obtained a product approval or made a product report under paragraphs (2) through (4). <Newly Inserted by Act No. 10512, Mar. 30, 2011>

(8) No person who falls under any of the following subparagraphs shall obtain approval nor submit a report on manufacture business or contract manufacture of drugs, etc.:

1. A person falling under any subparagraph of Article 5;
2. A person, for whom one year has not passed since the revocation of a license of manufacture business or closure of an office of a contract manufacture or a factory pursuant to Article 76;
3. A person who was declared bankrupt and has not been reinstated.

(9) In cases under paragraphs (1) through (4), when intending to change the permitted or reported matters prescribed by Ordinance of the Ministry of Health and Welfare, he/she shall obtain approval for a change or submit a report on a change, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008>

(10) Any product subject to approval or report under paragraphs (2) and (3) is a new drug or a drug designated by the Commissioner of the Korea Food and Agriculture Administration, the following documents related to safety and efficacy shall be submitted, as prescribed by Ordinance of the Ministry of Health and Welfare: *Provided*, That subparagraph 2 shall be excluded in cases where active pharmaceutical ingredients are registered under Article 31-2: <Amended by Act No. 10512, Mar. 30, 2011>

1. Test results and data related thereto;
2. Data on active pharmaceutical ingredients;
3. Related literature;
4. Other necessary data.

(11) When obtaining a license for or submitting a report on manufacture business, contract manufacture and manufacture and sale of drugs, etc. under paragraphs (1) through (4) and (9), matters necessary for the products, standards, conditions, management, etc. of a license or reporting shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008>

[This Article Wholly Amended by Act No. 8643, Oct. 17, 2007]

Article 32 (Re-Examination of New Drugs, etc.)

(1) Drugs under Article 31 (8), product approval of which has been granted pursuant to Article 31 (2) and (3) shall undergo a re-examination by the Commissioner of the Korea Food and Drug Administration, within three months after four to six years have passed since the date of approval. <Amended by Act No. 8643, Oct. 17, 2007>

(2) Matters necessary for method, procedure, time, etc. for re-examination referred to in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 33 (Re-Evaluation of Drugs)

(1) The Commissioner of the Korea Food and Drug Administration may re-evaluate drugs, for which examination of safety and efficacy by effect or ingredient, or the verification of drug equivalence is deemed necessary, among drugs, product approval of which has been granted or a product report of which has been made pursuant to Article 31 (2) and (3). *<Amended by Act No. 8643, Oct. 17, 2007>*

(2) Matters necessary for methods of, procedures, etc. for re-evaluation referred to in paragraph (1) shall be determined by the Commissioner of the Korea Food and Drug Administration.

Article 34 (Permission of Clinical Trial Protocol, etc.)

(1) Any person who intends to conduct a clinical trial using drugs, etc. shall work out a clinical trial protocol and obtain permission thereof from the Commissioner of the Korea Food and Drug Administration. The same shall apply in cases where he/she intends to alter the permitted clinical trial protocol.

(2) Any person who intends to conduct a clinical trial under paragraph (1) shall be prohibited from selecting any person (hereafter referred to as “accommodated person” in this paragraph) accommodated in a collective establishment, including social welfare establishments, etc., prescribed by Ordinance of the Ministry of Health and Welfare, as a testee of such clinical trial: However, where the selection of an accommodated person as a testee is inevitable in light of the characteristics of the clinical trial and such selection conforms to the standards prescribed by Ordinance of the Ministry of Health and Welfare, he/she may select an accommodated person as a testee of a clinical trial. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(3) Where a clinical trial which is subject to permission under paragraph (1) is deemed or feared to harm the public interest or health and sanitation from pharmaceutical preparations containing questionable ingredients in light of safety or efficacy, blood derivative products, gene therapy products and cell therapy products, etc.

the Commissioner of the Korea Food and Drug Administration may place limits on such clinical trial.

(4) Any person who intends to conduct a clinical trial referred to in paragraph (1) shall explain details of such clinical trial and details of and procedures, etc. for an indemnity for any health damage that may be inflicted on a testee during the clinical trial to such testee and then obtain consent of the testee.

(5) Any person who intends to conduct a clinical trial referred to in paragraph (1) shall use drugs, etc. which are manufactured or imported after being manufactured in a manufacturing establishment which conforms to standards prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010 >*

(6) Where any clinical trial, permission or alteration permission for which is granted under paragraph (1), is conducted in violation of approved or alteration-approved matters, or serious safety and ethical questions are raised with respect to such clinical trial, the Commissioner of the Korea Food and Drug Administration may order that necessary steps shall be taken to halt using drugs, etc. for the clinical trial and recall or dispose of such drugs, etc.

(7) Matters to be included in a clinical trial protocol referred to in paragraphs (1) and (4), details of the consent of a testee and the timing and methods thereof, standards for conducting a clinical trial and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010 >*

Article 35 (Conditional Approval)

(1) In granting approval under Article 31 (1) and (2), the Commissioner of the Korea Food and Drug Administration may grant approval for the manufacturing business of drugs or products prescribed by Ordinance of the Ministry of Health and Welfare, on condition that the facilities referred to in Article 31 (1) shall be established within a fixed period. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010 >*

(2) If a person who has obtained approval under paragraph (1) fails to establish proper facilities without justifiable grounds within a period under paragraph (1), the Commissioner of the Korea Food and Drug Administration shall cancel such

approval.

Article 36 (Pharmaceutical Manufacturing Supervisors, etc.)

(1) A manufacturer of drugs or quasi-drugs (excluding a manufacturer of quasi-drugs who manufactures only products falling under subparagraph 7 (a) of Article 2) shall assign the necessary number of pharmacists or oriental pharmacists to each production facility and entrust them with supervision over manufacturing affairs, as prescribed by Ordinance of the Ministry of Health and Welfare: However, in the biological preparation manufacturing industry, he/she may entrust a doctor or a technician with bacteriological knowledge, approved by the Commissioner of the Korea Food and Drug Administration, with supervision over the manufacturing affairs thereof. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) A manufacturer of quasi-drugs who manufactures only the products falling under subparagraph 7 (a) of Article 2 shall assign a technician approved by the Commissioner of the Korea Food and Drug Administration to each of his/her production facilities and entrust them with supervision over manufacturing affairs: However, in cases where the manufacturer himself/ herself is a technician approved by the Commissioner of the Korea Food and Drug Administration, and supervises manufacturing affairs at his/her production facility, he/she may choose not to assign an additional technician to such production facility.

Article 37 (Duty to Supervise Manufacturing Drugs, etc.)

(1) Any manufacturing supervisor shall observe matters prescribed by Ordinance of the Ministry of Health and Welfare with regard to guidance and supervision of employees engaging in the affairs of manufacturing drugs, etc., quality control, management of manufacturing facilities, and other matters concerning manufacturing supervision. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) No manufacturing supervisor shall engage in business, other than manufacture-supervising duties for the relevant production facility.

(3) No manufacturer or person who has obtained product approval shall interfere with the supervisory affairs of a manufacturing supervisor, nor refuse, without justifiable grounds, any request from a manufacturing supervisor on the matters necessary for carrying out his/her duties. *<Amended by Act No. 8643, Oct. 17, 2007>*

Article 37-2 (Post-market Safety Management of Drugs)

(1) A person who has obtained product approval shall employ pharmacists or oriental pharmacists to have them perform affairs of safety control after sale at a market, such as re-examination of new drugs, etc, re-evaluation of drugs, reporting on adverse drug reactions, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) A person who performs affairs of safety control under paragraph (1) (hereinafter referred to as “safety control manager”) shall observe matters prescribed by Ordinance of the Ministry of Health and Welfare with respect to safety control of drugs under distribution.

*[This Article Newly Inserted by Act No. 8643, Oct. 17, 2007]*

Article 38 (Duty of Production Management of Drugs, etc. and Reporting thereof)

(1) Manufacturers of drugs or persons who have obtained product approval, etc. shall observe matters prescribed by Ordinance of the Ministry of Health and Welfare with respect to the manufacture and quality control (including self test) of drugs, etc. and other production supervision thereof. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) A person who has obtained product approval or a manufacturer of quasi-drugs shall report the production performance of drugs, etc. to the Commissioner of the Korea Food and Drug Administration or the president of the Korea Pharmaceutical Information Service under Article 47-2 (1), as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 39 (Recall of Hazardous Drugs, etc.)

(1) When those prescribed by Ordinance of the Ministry of Health and Welfare, among persons who have obtained product approval, manufacturers of quasi-drugs or importers and sellers of drugs, etc., pharmacy founders, medical institution founders and other persons who are eligible to sell or deal with drugs pursuant to this Act or other Acts, become aware of that the drugs, etc. have a problem in the safety and efficacy in violation of Article 53 (1), 61 (including cases where it applies *mutatis mutandis* in Article 66) or 62 (including cases where it applies *mutatis mutandis* in Article 66), they shall promptly recall the drugs, etc. in distribution or take necessary measures for recall. In such cases, persons who have obtained

product approval, manufacturers of quasi-drugs or importers of drugs, etc. shall report a recall plan to the Commissioner of the Korea Food and Drug Administration in advance. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(2) The Commissioner of the Korea Food and Drug Administration, Mayors/Do Governors or heads of *Sis/Guns/Gus* may grant mitigation or remission of the administrative disposition pursuant to Article 76 to persons who have obtained product approval, manufacturers of quasi-drugs or importers of drugs, etc., pharmacy founders and distributors of drugs who conscientiously perform the recall or take measures necessary for the recall in accordance with paragraph (1), as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(3) Matters necessary for the classification of hazard and standards for appraisal necessary for the recall of drugs, etc. pursuant to paragraph (1), plans for recall, procedures for recall, discard of recalled drugs and post-measures, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

#### Article 40 (Reporting on Discontinuance of Business)

In cases where a manufacturer of drugs, etc. or a person who has obtained product approval falls under any of the following subparagraphs, he/she shall report to the Commissioner of the Korea Food and Drug Administration within twenty days: However, the same shall not apply in cases where a period for suspension of business is under one month:

1. In cases where a factory or an office of contract manufacture is closed or suspended;
2. In cases where a suspended factory or office of contract manufacture is reopened;
3. In cases where a manufacturing supervisor, a safety control manager and other matters prescribed by Ordinance of the Ministry of Health and Welfare are changed.

[This Article Wholly Amended by Act No. 8643, Oct. 17, 2007]

#### Article 41 (Manufacturing Pharmacy Medication)

(1) When a pharmacy founder intends to manufacture pharmacy medications, or a dispensary of a medical institution designated by the Minister of Health and

Welfare intends to make medications, they shall report the relevant products to the head of a *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare: However, where a dispensary of a medical institution which has been established by permission from a Mayor/Do Governor pursuant to the Medical Service Act intends to make medications, they shall report to the relevant Mayor/Do Governor. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(2) The scope of pharmacy medication and dispensary medication, facilities of dispensaries and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

## SECTION 2 Approval, etc. for Importation of Drugs, etc.

### Article 42 (Approval, etc. for Importation of Drugs, etc.)

(1) Any person who intends to import drugs, etc. (hereinafter referred to as “importer”) shall obtain approval by product from or file a report with the Commissioner of the Korea Food and Drug Administration by product, as prescribed by Ordinance of the Ministry of Health and Welfare. The same shall also apply in cases where he/she intends to modify the approved or reported matters. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010 >

(2) Notwithstanding the provisions of paragraph (1), the Minister of National Defense or importers may import drugs without receiving approval or making a report by product under paragraph (1), in cases falling under any of the following subparagraphs: <Amended by Act No. 10512, Mar. 30, 2011>

1. When the Minister of National Defense desires to import drugs, etc. not produced in Korea, for any urgent military purpose, he/she may import them with prior consultation with the Commissioner of the Korea Food and Drug Administration on the products and quantity thereof;
2. When importers intend to import active pharmaceutical ingredients to manufacture drugs, etc. or import drugs prescribed by Ordinance of the Ministry of Health and Welfare, such as drugs for clinical tests.

(3) An importer shall have necessary facilities in conformity with the

standards of installation prescribed by Presidential Decree.

(4) The provisions of Articles 31 (8) and (9), 32, 33, 36, 37, 37-2, 38, and 75 shall apply *mutatis mutandis* to drugs, etc. that are imported pursuant to paragraph (1) or to an importer thereof. In such cases, “manufacture” or “production” shall be construed as “importation”, and “manufacturers or persons who have obtained product approval” shall be construed as “importers” *<Amended by Act No. 8643, Oct. 17, 2007>*

(5) In granting approval for the importation of medicinal products, etc. referred to in paragraph (1), the matters necessary for the subject matters, standards, condition, control, etc. of approval, shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 43 (International Trade, etc. in Endangered Species of Wild Fauna and Flora)

(1) Any person who desires to export, import, or carry into Korea by sea, drugs made from processed goods of animals and plants as prescribed by the Convention on International Trade in Endangered Species of Wild Fauna and Flora, shall obtain approval from the Commissioner of the Korea Food and Drug Administration, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) No person shall commit any of the following acts with respect to the horns of rhinoceroses or the bones of tigers, which are processed goods using endangered species of wild animals:

1. Importing or selling the horns of rhinoceros or the bones of tigers, or storing or displaying them for sale;
2. Manufacturing or dispensing drugs made from the horns of rhinoceros or bones of tigers;
3. Selling any drugs manufactured or dispensed using the horns of rhinoceros or the bones of tigers, or storing or displaying them for sale.

### SECTION 3 Distribution Business of Drugs, etc.

Article 44 (Distribution of Drugs)

(1) No person, other than pharmacy founders (including pharmacists or oriental

pharmacists working for such pharmacy; hereafter the same shall apply in Articles 47, 48 and 50) shall sell drugs or acquire drugs for sale: However, the same shall not apply in cases where a person who has obtained product approval or an importer of drugs sells drugs manufactured or imported to a person who can manufacture or sell drugs according to this Act. *<Amended by Act No. 8643, Oct. 17, 2007>*

(2) Notwithstanding the provisions of paragraph (1), any of the following persons shall be eligible to sell drugs or acquire drugs for sale:

1. Korea Orphan Drug Center established pursuant to Article 91;
2. Herb druggists or drug wholesalers permitted pursuant to Article 45.

Article 45 (Licenses of Drug Distribution Business)

(1) A person who intends to become a herb druggist or drug wholesaler pursuant to Article 44 (2) 2 shall be licensed by the head of a *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare. The same shall apply to the modification of the licensed matters. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) A person who intends to obtain a license pursuant to paragraph (1) shall have the facilities meeting the standards of facilities prescribed by Presidential Decree.

(3) A license of a herb druggist pursuant to paragraph (1) shall be granted to a person who has passed a herb druggist examination prescribed by Presidential Decree by limiting districts prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(4) A herb druggist who has obtained a license pursuant to paragraph (1) may sell herbal materials after mixing them in accordance with a prescription recorded in an established herb book or with a prescription of an oriental pharmacist.

(5) A drug wholesaler who has obtained a license pursuant to paragraph (1) shall employ a pharmacist and have him/her administer duties, and a herb wholesaler shall employ any of the following persons and have him/her administer duties: However, in cases where the drug wholesaler who himself/herself is a pharmacist administers duties in person, or the herb wholesaler who falls under any of the following subparagraphs administers duties in person, this shall not apply: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

1. A pharmacist;

2. An oriental pharmacist;
3. A herb druggist;
4. A person who has completed a herb-related course of a college or university accredited by the Minister of Health and Welfare.

(6) When a drug wholesaler or herb wholesaler intends to employ a person who administers duties under paragraph (5), he/she shall report to the head of a *Si/Gun/Gu*, as prescribed by Ordinance of the Ministry of Health and Welfare.

(7) Matters necessary for the standards, conditions and management of approval pursuant to paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011>*

#### Article 46 (Grounds for Disqualification as Herb Druggists or Drug Wholesalers)

No person who falls under any of the following subparagraphs shall be disqualified as a herb druggist or drug wholesaler:

1. A person falling under any subparagraph of Article 5;
2. A person for whom one year has not passed after his/her license was revoked pursuant to Article 76;
3. A founder of a medical institution (where the medical institution is a juristic person, the executives and employees thereof);
4. A person who was declared bankrupt but has not yet been reinstated.

#### Article 47 (Order in Distribution of Drugs, etc.)

(1) A pharmacy founder, a person who has obtained product approval, an importer and a distributor of drugs and other persons who are entitled to sell drugs pursuant to this Act shall abide by the matters necessary to establish a distribution system of drugs, etc. and to maintain distribution order, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) No person who has obtained product approval, importer and wholesaler of drugs shall offer any money, articles, labor, entertainment or other economic interest (hereinafter referred to as “economic interest , etc.”) to a pharmacist, oriental pharmacist (including persons working for the relevant pharmacy; hereafter the same shall apply in this Article), medical personnel, medical institution founders (including

the representative, director and other employees of a juristic person) or persons working for the relevant medical institution for the purpose of sales promotion, such as adoption of drugs or inducement of prescription: However, the same shall not apply to the economic interest, etc. within the scope determined by Ordinance of the Ministry of Health and Wealth, such as provision of samples, support of symposiums, support for clinical trials, product presentation, discount of expenses pursuant to price payment conditions, and post-marketing survey (hereinafter referred to as “provision, etc. of samples”). *<Newly Inserted by Act No. 10324, May 27, 2010>*

(3) No pharmacist and oriental pharmacist shall receive any economic interest, etc. from a person who has obtained product approval, an importer and a wholesaler of drugs for the purpose of sales promotion, such as adoption of drugs: However, the same shall not apply to the economic interest, etc. within the scope determined by Ordinance of the Ministry of Health and Welfare, such as provision, etc. of samples. *<Newly Inserted by Act No. 10324, May 27, 2010>*

#### Article 48 (Prohibition of Sale of Unsealed Drugs)

No person shall sell drugs, etc. after breaking the seal of a container or package sealed by manufacturers, persons who have obtained product approval or importers pursuant to Article 63: However, the same shall not apply in any of the following cases: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

1. Where a pharmacy founder dispenses and sells drugs according to prescriptions made by a doctor, dentist or oriental pharmacist, or pursuant to the provisos to Article 23 (3) and (6) or to Article 4 of the Addenda of the Pharmaceutical Affairs Act amended by Act No. 4731;
2. Where a pharmacy founder sells dispensed herbal materials after opening them;
3. Where a person designated by the Minister of Health and Welfare opens and sells drugs within the scope prescribed by Ordinance of the Ministry of Health and Welfare.

#### Article 49 (Restrictions on Products for Sale by Drug Sellers)

No drug seller shall sell drugs, other than those designated separately by the Minister of Health and Welfare, nor store or display them for sale. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*



## Article 50 (Distribution of Drugs)

(1) No pharmacy founder or drug distributor shall sell drugs at a place, other than his/her pharmacy or shop: However, the same shall not apply in cases where approval therefor is obtained from the head of a *Si/Gun/Gu*.

(2) No pharmacy founder shall sell any prescription drugs except for cases of dispensing them in accordance with a prescription issued by a doctor or dentist: However, the same shall not apply in cases where such drugs are sold to any person who has established a veterinary hospital in accordance with the Veterinarians Act, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(3) Any pharmacy founder may sell any over-the-counter drugs without prescriptions issued by a doctor or a dentist.

(4) Where any pharmacy founder deems it necessary to sell over-the-counter drugs, he/she may offer medication consulting.

## CHAPTER VI HANDLING OF DRUGS, ETC.

## SECTION 1 Standard and Product Testing

## Article 51 (Korean Pharmacopoeia)

(1) In order to ensure the appropriateness in the nature, efficacy, quality, and methods of manufacturing and storing drugs, the Commissioner of the Korea Food and Drug Administration shall enact a Korean Pharmacopoeia through deliberation by the Central Pharmaceutical Affairs Council, and shall announce it publicly.

(2) The Korean Pharmacopoeia shall be divided into Parts I and II: raw drugs that are frequently used and the basic preparation of drugs shall be mainly listed in Part I, and the mixed preparation of drugs and the drugs not listed in Part I, shall be mainly listed in Part II.

## Article 52 (Standard for Drugs, etc.)

(1) With regard to antibiotic substances and their preparations, biological preparations, and drugs which are not listed in the Korean Pharmacopoeia and require special attention from the public health and sanitary point of view, the Commissioner of the Korea Food and Drug Administration may, after consultation with the Central

Pharmaceutical Affairs Council, determine the nature, efficacy, quality, and methods of manufacturing and storing drugs, and other necessary criteria thereof.

(2) When the Commissioner of the Korea Food and Drug Administration deems it necessary for the prevention of any danger or harm to the public health and sanitation, he/she may, after consultation with the Central Pharmaceutical Affairs Council, determine the nature, efficacy, quality, and methods of manufacturing and storing quasi-drugs and other necessary standard thereof.

## Article 53 (Drugs Under National Lot Release)

(1) Drugs prescribed by Ordinance of the Ministry of Health and Welfare (hereinafter referred to as “drugs under national lot release”), among those falling under any of the following subparagraphs, shall not be sold or displayed, kept or stored for sale, if they have not passed an inspection of the Commissioner of the Korea Food and Drug Administration: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

1. Biologically prepared drugs;
2. Drugs liable to be changed or spoiled in quality;
3. Other preparation of drugs deemed necessary by the Commissioner of the Korea Food and Drug Administration.

(2) The inspection of drugs under national lot release under paragraph (1) and other necessary matters, shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

## Article 54 (Radiopharmaceuticals)

The Commissioner of the Korea Food and Drug Administration may determine necessary matters concerning manufacturing and importation of radiopharmaceuticals after consultation with the Minister of Science and Technology.

## Article 55 (Abusive or addictive Drugs)

Matters necessary for the manufacturing and management of potentially abusive or addictive drugs shall be determined by a separate Act.

## SECTION 2 Handling of Drugs

## Article 56 (Labelling on Containers, etc.)

A person who has obtained product approval and importer of drugs shall enter the following matters on the containers or packages of drugs; However, in cases of the containers or packages prescribed by Ordinance of the Ministry of Health and Welfare, some of the following matters may be omitted, or only some of the following matters may be included, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

1. Trade name and address of a person who has obtained product approval or an importer (in cases of contract manufacture, trade name and address of a factory);
  2. Name (as for drugs listed in the Korean Pharmacopoeia, the names provided for in such Pharmacopoeia, and as for other drugs, general names);
  3. Manufacturing number and effective period or time-limit for use;
  4. Weight, capacity, or number of products;
  5. Matters to be described in containers or packages as prescribed by the Korean Pharmacopoeia;
  6. As for the drugs, the standards for which are determined under Article 52 (1), the methods of storing such drugs and other matters to be stated on the containers or packages in accordance with such standards;
  7. As for the drugs not listed in the Korean Pharmacopoeia, names of active ingredients (if there are general names, such names shall be stated) and quantity (if active ingredients are not clear, the essence thereof and outline of manufacturing methods shall be stated);
  8. Letters of “prescription drug” or “over-the-counter drug”;
  9. Matters provided for in subparagraphs 1 through 3 of Article 58;
  10. Other matters prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) Persons who sell drugs in person to consumers, including pharmacy founders, shall state the prices of drugs on the containers or packages of drugs, as prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Act No. 10788, Jun. 7, 2011]

#### Article 57 (Labelling on Outside Packages)

If the matters listed in each subparagraph of Article 56 (1), which have been stated

on the immediate container or package of drugs, are not visible because they are obstructed by the outside container or wrapper, such matters shall also be stated on the outside container or wrapper.

#### Article 58 (Labelling on Leaflets)

The following matters shall be stated in leaflets: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

1. Directions, doses, and other precautions necessary for use or handling;
2. As for the drugs listed in the Korean Pharmacopoeia, matters to be stated on leaflets, containers, or packages thereof provided for in the Korean Pharmacopoeia;
3. As for the drugs, the standards for which are determined under Article 52 (1), matters to be stated on leaflets, containers, or packages thereof in accordance with such standards;
4. Other matters prescribed by Ordinance of the Ministry of Health and Welfare.

#### Article 59 (Precautions on Labelling)

Matters provided for in Articles 56 through 58 shall be stated on places which are more easily seen than other letters, news articles, pictures or designs, and such matters shall be stated precisely in easy and understandable terms, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

#### Article 60 (Labelling Prohibited from being Stated)

The following matters shall not be stated on leaflets, containers or packages of drugs: <Amended by Act No. 8643, Oct. 17, 2007>

1. False matters or those apprehended to be misunderstood with regard to the drug concerned;
2. Indication which has not been permitted or reported pursuant to Article 31 (2) and (3) or 41 (1);
3. Direction, dosage or period of use which is dangerous to public health and sanitation.

#### Article 61 (Prohibition of Distribution, etc.)

(1) No one shall sell, or store or display the following drugs for sale: <Amended by Act No. 8643, Oct. 17, 2007>

1. Drugs in violation of the provisions of Articles 56 through 60 or fake drugs;

2. Drugs manufactured or imported in violation of Articles 31 (2) and (3), 41 (1), 42 (1) and (3), and 43 (1).

(2) No one shall put a mark on a container, package or leaflet, which is apprehended to make a product, other than drugs, misunderstood as having medical indication, or shall put an advertisement of these contents, sell a product indicated or advertised like drugs, store or display them for sale.

Article 62 (Prohibition of Manufacturing, etc.)

No one shall sell the following drugs or manufacture, import, store or display them for sale: <Amended by Act No. 8643, Oct. 17, 2007>

1. Drugs which are listed in the Korean Pharmacopoeia, but whose nature, efficacy or quality does not meet the standards specified in the Korean Pharmacopoeia;
2. Drugs which are permitted or reported under Articles 31 (2) and (3) and 41 (1), but whose ingredients or quantities (if active ingredients are not clear, the essence thereof or outline of manufacturing methods) are different from the details permitted or reported;
3. Drugs whose standards are determined under Article 52 (1), but which do not meet such standards;
4. Drugs, all or some of which are made from unclean, or degenerated or spoiled materials;
5. Drugs which are tainted or deemed to have been tainted by pathogens that may cause a disease;
6. Drugs which alien substances are mixed with or adhered to;
7. Drugs in which tar pigment, other than that determined by the Commissioner of the Korea Food and Drug Administration, is used;
8. Drugs which are manufactured under unsanitary circumstances that might harm public health and sanitation, or which are manufactured at a place where the manufacturing equipment fails to meet standards prescribed by Presidential Decree;
9. Drugs which are feared to harm public health and sanitation due to their unsanitary containers or packages;
10. Drugs whose containers or packages might make users misunderstand the method

of using them;

11. Drugs falling under Article 76 (1) 4.

Article 63 (Sealing)

If a manufacturer, a person who has obtained product approval, or an importer of drugs sells drugs manufactured or imported by himself/herself, he/she shall seal the containers or packages of such drugs, as prescribed by Ordinance of the Ministry of Health and Welfare: However, this shall not apply in cases where he/she sells them to a manufacturer or a person who has obtained product approval. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 64 (Safety Containers or Packages, etc.)

(1) Where a person who has obtained product approval or an importer of drugs sells drugs manufactured or imported by him/herself, he/she shall use safety containers or packages in order to prevent the accidents of drugs by children due to misuses: However, the same shall not apply in cases where they are sold to manufacturers or persons who have obtained product approval. <Amended by Act No. 8643, Oct. 17, 2007>

(2) Products which shall use safety containers or packages and criteria, etc. for safety containers or packages shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

### SECTION 3 Quasi-Drugs

Article 65 (Labelling on Containers, etc.)

Manufactures and importers of quasi-drugs shall state the following matters on the containers, packages, or leaflets (only in cases where leaflets exist) of quasi-drugs: However, only the names of quasi-drugs and firm names of manufactures and importers shall be stated on the containers or packages prescribed by Ordinance of the Ministry of Health and Welfare: <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

1. Names of quasi-drugs (excluding products under subparagraph 7 (a) of Article 2);
2. Firm name and address of a manufacturer or importer;

3. Capacity or weight (capacity, weight or number, in cases of products under subparagraph 7 (a) of Article 2);
4. Batch number and manufactured date;
5. Names of major ingredients (excluding products under subparagraph 7 (a) of Article 2);
6. For products, the standards for which are determined under Article 52 (2), the methods of storing them, and other matters to be stated on the container or package under such standards;
7. For quasi-drugs, the letter of “quasi-drugs”;
8. Other matters prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Wholly Amended by Act No. 10788, Jun. 7, 2011]

#### Article 66 (Application *Mutatis Mutandis*)

The provisions of Articles 60 through 63 (Articles 60 through 62 in cases of products falling under subparagraph 7 (a) of Article 2 from among quasi-drugs) shall apply *mutatis mutandis* to quasi-drugs. In such cases, “drugs” shall be construed as “quasi-drugs”.

### SECTION 4 Pharmaceutical Organizations

#### Article 67 (Organization)

Manufacturers, persons who have obtained product approval, importers of drugs, or distributors of drugs may organize an incorporated association respectively in order to secure independent activities and common interests and to contribute to the improvement of national public health. <Amended by Act No. 8643, Oct. 17, 2007>

### SECTION 5 Advertisement of Drugs, etc.

#### Article 68 (Prohibition of Exaggerated Advertisement, etc.)

- (1) Names, manufacturing methods, efficacy, or performance of drugs, etc. shall not be advertised falsely or exaggeratedly.
- (2) No article shall be used to make people misunderstand that doctors, dentists, oriental pharmacists, veterinarians or other persons guarantee the efficacy or performance of drugs, etc.

- (3) No efficacy or performance of drugs, etc. shall be advertised by suggestive articles, photographs, designs and other suggestive methods.
- (4) No documents or designs which suggest induced abortion shall be used with respect to drugs.
- (5) Names, manufacturing methods, efficacy or performance of drugs, etc. shall not be advertised without obtaining approval or submitting a report, as prescribed by Article 31 (2) and (3) or 42 (1). <Amended by Act No. 8643, Oct. 17, 2007>
- (6) Necessary matters for the scope and other matters of advertisement of drugs, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

#### Article 68-2 (Deliberation on Advertisement)

- (1) In cases where a manufacturer, a person who has obtained product approval or an importer of drugs intends to advertise such drugs manufactured or imported, he/she shall undergo deliberation by the Commissioner of the Korea Food and Drug Administration, as prescribed by Ordinance of the Ministry of Health and Welfare.
- (2) The Commissioner of the Korea Food and Drug Administration may entrust an association incorporated pursuant to Article 67 with affairs concerning deliberation on advertisement of drugs.
- (3) Procedures for and methods of deliberation on advertisement under paragraph (1) and matters necessary for raising an objection against the results of deliberation, revising details of deliberation and indicating deliberation results shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted by Act No. 8643, Oct. 17, 2007]

### SECTION 6 Korea Pharmaceutical Safety Control Institute

#### CHAPTER VII SUPERVISION

#### Article 69 (Reporting, Inspection, etc.)

- (1) The Minister of Health and Welfare, the Commissioner of the Korea Food and Drug Administration, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may order the following matters: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb.

29, 2008; Act No. 9932, Jan. 18, 2010>

1. Ordering pharmacy founders, medical institution founders, manufacturers, persons who have obtained product approval, importers or distributors of drugs, etc., and other persons engaged in the business of handling drugs, etc. to submit necessary documents or other data;
  2. Ordering the relevant public officials to enter pharmacies, medical institutions, factories, warehouses, shops, or offices that manufacture, store or handle drugs, etc., or other places where drugs, etc. are handled for business, and inspect the facilities concerned, relevant books and documents or other articles, or query to persons concerned;
  3. Collecting the minimum quantity of articles necessary for quality inspection into products, drugs, etc. which are suspected to fall under Article 71 (1).
- (2) Any public official who performs an inspection under paragraph (1) shall carry with him/her a certificate indicating such authority and produce it to persons concerned.
- (3) The authority and the scope of duties of pertinent public officials and other necessary matters under paragraph (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 70 (Order to Commence Business, etc.)

- (1) If it is recognized that drug manufacturers, persons who have obtained product approval, pharmacy founders, or drug distributors cause or are likely to cause remarkable impediment in the purchase of drugs through joint suspension of production and sale of drugs, collective business suspension, or closure, the Minister of Health and Welfare, the Commissioner of the Korea Food and Drug Administration, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may order them to commence production of drugs or performance of duties. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010 >
- (2) No drug manufacturer, person who has obtained product approval, pharmacy founder, or drug distributor shall refuse an order referred to in paragraph (1) without justifiable grounds. <Amended by Act No. 8643, Oct. 17, 2007>

Article 71 (Order, etc. of Scrapping)

- (1) The Commissioner of the Korea Food and Drug Administration, a Mayor/Do

Governor, or the head of a *Si/Gun/Gu* may order persons who have obtained product approval, manufacturers of quasi-drugs, importers or distributors of drugs, etc., pharmacy founders, medical institution founders, or other persons prescribed by Ordinance of the Ministry of Health and Welfare among persons eligible to sell or deal with drugs pursuant to this Act or other Acts to scrap the drugs, etc. which have been sold, stored, displayed, manufactured or imported in violation of Articles 53 (1), 61 (including cases where it applies *mutatis mutandis* in Article 66), and 62 (including cases where it applies *mutatis mutandis* in Article 66) or bad drugs, etc. or raw materials and materials thereof, etc. in a manner that prevents hazards to public health or to take other necessary measures. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(2) When any drug, etc. actually harms or is likely to harm public health, the Commissioner of the Korea Food and Drug Administration, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may order persons who have obtained product approval, manufacturers of quasi-drugs, importers or distributors of drugs, etc., or pharmacy founders, medical institution founders, or other persons prescribed by Ordinance of the Ministry of Health and Welfare among persons eligible to sell or deal with drugs pursuant to this Act or other Acts, to recall and scrap such drug, etc. under distribution or to take other necessary measures. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(3) In cases where any person who has been ordered pursuant to paragraph (1) or (2) fails to comply with such order, or in cases of emergency for public health, the Commissioner of the Korea Food and Drug Administration, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may have the competent public officials recall and scrap the relevant drug, etc., or take other necessary measures.

(4) The provisions of Article 69 (2) shall apply *mutatis mutandis* to paragraph (2).

(5) The grades of harms and standards for appraisal of drugs, etc., recall and scrapping of drugs, etc. and matters necessary for other measures, etc. pursuant to paragraph (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 72 (Announcement of Recall, etc. of Drugs, etc.)

(1) When the Commissioner of the Korea Food and Drug Administration receives a report on a plan for recall of drugs, etc. pursuant to the latter part of Article 39 (1), he/she may order persons who have obtained product approval, manufacturers of quasi-drugs or importers of drugs, etc. to announce the recall plan. <Amended by Act No. 8643, Oct. 17, 2007>

(2) Where the Commissioner of the Korea Food and Drug Administration, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* has ordered to recall and scrap drugs, etc. under distribution, or to take other necessary measures pursuant to Article 71 (2), he/she shall order persons who have obtained product approval, manufacturers of quasi-drugs, importers or distributors of drug, etc., pharmacy founders, medical institution founders, or other persons prescribed by Ordinance of the Ministry of Health and Welfare from among persons eligible to sell or deal with drugs pursuant to this Act or other Acts, to announce such fact. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(3) The method of announcement and other matters necessary for announcement pursuant to paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

#### Article 73 (Order of Inspection)

The Commissioner of the Korea Food and Drug Administration or a Mayor/Do Governor may order a manufacturer or importer of drugs, etc., to undergo inspection into the manufactured or imported drugs, etc. by a person designated by the Commissioner of the Korea Food and Drug Administration or the Mayor/Do Governor.

#### Article 74 (Repair Order)

When facilities fail to meet the standards for facilities pursuant to Articles 20 (3), 31 (1) and (4), 42 (3) and 45 (2), or facilities have become old, squalid or damaged, so that drugs, etc. manufactured by using such facilities are likely to fall under any subparagraph of Article 62 (including cases where it applies *mutatis mutandis* in Article 66), the Commissioner of the Korea Food and Drug Administration, a Mayor/Do Governor, or the head of a *Si/Gun/Gu* may order pharmacy founders, manufacturers, persons who have obtained product, importers or distributors of drugs, etc., to repair such facilities or may order them not to use all or some

of the facilities until the completion of repair. <Amended by Act No. 8643, Oct. 17, 2007>  
Article 75 (Order to Change Managers, etc.)

If a manager of a manufacturing business of drugs, etc. or a manager of a pharmacy has violated this Act or an order issued pursuant to this Act, or if the manager is deemed unsuited as a manager, the Commissioner of the Korea Food and Drug Administration may order the manufacturer concerned to change the manager, and the head of a *Si/Gun/Gu* may order the pharmacy founder concerned to change the manager of a pharmacy.

#### Article 76 (Revoke of Approval and Suspension of Business, etc.)

(1) If a manufacturer, a person who has obtained product approval, an importer of drugs, etc. a pharmacy founder, or a drug distributor falls under any of the following subparagraphs, the Commissioner of the Korea Food and Drug Administration, as for a manufacturer, a person who has obtained product approval or an importer of drugs, etc., and the Mayor/Do Governor or the head of a *Si/Gun/Gu*, as for a pharmacy founder or a drug distributor, may, respectively, revoke approval, recognition, registration, or close an office of a contract manufacture and a factory (limited to the types of business for which reports have been filed pursuant to the provisions of Article 31 (4); hereafter the same shall apply in subparagraph 1 of Article 77), or order a prohibition against manufacturing products or against importing products, or order a suspension of all or some of the business concerned for a specified period: However, in cases referred to in subparagraph 4, if he/she has no fault and if it is deemed that the purpose of approval or report could be achieved by changing the ingredients or prescriptions of the drugs, etc. concerned, only such change may be ordered: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10324, May 27, 2010>

1. Where he/she falls under any of subparagraphs 1 through 4 of Article 5;
2. Where it turns out that he/she falls under any subparagraph of Article 20 (5), or under Article 31 (4) 2;
3. Where he/she violates this Act or any order issued under this Act;
4. Where he/she manufactures, imports or sells drugs, etc. which have harmed or are likely to harm national public health, and drugs, etc. which are deemed to have no efficacy;

5. Where he/she fails to recall the relevant drugs or take measures necessary for recall pursuant to Article 39 (1);
- 5-2. Where he/she offers any economic interest, etc. in violation of Article 47 (2);
6. Where a pharmacy founder has received a disposition of suspension of qualification as a pharmacist or oriental pharmacist under Article 79 (2).
- (2) In cases where the facilities of the persons referred to in paragraph (1), do not meet the standards for facilities prescribed by Articles 20 (3), 31 (1) and (4), 42 (3) and 45 (2), the same as paragraph (1) shall apply thereto. *<Amended by Act No. 8643, Oct. 17, 2007>*
- (3) The criteria for an administrative disposition under paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

## Article 77 (Hearings)

The Minister of Health and Welfare, the Commissioner of the Korea Food and Drug Administration, a Mayor/Do Governor or the head of a *Si/Gun/Gu* who desires to render a disposition falling under any of the following subparagraphs shall hold a hearing: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

1. Cancelling approval, recognition, registration, or closure of an office of a contract manufacture and a factory, or issuing orders to prohibit manufacturing or importing of products under Article 76;
2. Cancelling a license under Article 79 (1) or (2).

## Article 78 (Pharmaceutical Inspectors)

- (1) Pharmaceutical inspectors shall be assigned to the Korea Food and Drug Administration, *Cities/Dos, Sis/Guns/Gus* (referring to autonomous *Gus* of the Special Metropolitan City and Metropolitan Cities) in order to have them perform the duties of pertinent public officials under Articles 69 (1) and 71 (2).
- (2) Pharmaceutical inspectors shall be appointed by the Commissioner of the Korea Food and Drug Administration, Mayors/Do Governors or the heads of *Sis/Guns/Gus* from among public officials belonging to the Korea Food and Drug Administration, *Cities/Dos* or *Sis/Guns/Gus*.

- (3) Necessary matters concerning qualification, appointment, etc. of pharmaceutical inspectors shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

## Article 79 (Cancellation, etc. of Pharmacist's or Herb Pharmacist's License)

- (1) If a pharmacist or oriental pharmacist falls under any of subparagraphs 1 through 4 of Article 5, the Minister of Health and Welfare shall cancel his/her license. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*
- (2) If a pharmacist or oriental pharmacist falls under any of the following subparagraphs, the Minister of Health and Welfare may cancel his/her license or order the suspension of qualification as a pharmacist or oriental pharmacist, by up to one year: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

1. When he/she violates the Acts and subordinate statutes concerning pharmaceutical affairs or violates the criteria for ethics prescribed by Ordinance of the Ministry of Health and Welfare;
2. When he/she forges or alters the relevant documents or demands drug expenses by fraudulent and other illegal means.
- (3) In cases where a pharmacist or an oriental pharmacist falls under any of the following subparagraphs, the Minister of Health and Welfare may order the suspension of qualification as a pharmacist or an oriental pharmacist by up to one year: *<Newly Inserted by Act No. 9123, Jun. 13, 2008; ; Act No. 9932, Jan. 18, 2010; Act No. 10324, May 27, 2010>*
  1. Where he/she has been employed by a person disqualified as a pharmacy founder and performs affairs of a pharmacist or an oriental pharmacist;
  2. Where he/she receives any economic interest, etc. in violation of Article 47 (3).
- (4) Even though a pharmacist's or oriental pharmacist's license is cancelled under paragraphs (1) and (2), if a ground for the cancellation ceases to exist, the Minister of Health and Welfare may regrant the license, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

## Article 80 (Renewal of Certificate of License, Approval, Registration, etc.)

A person who has obtained a pharmacist's license or an oriental pharmacist's license,

a person who has registered opening of a pharmacy, a person who has obtained approval for a manufacture business or has reported a contract manufacture, etc., or a person who has obtained approval for distribution of drugs shall renew his/her license, permit or certificate of registration, etc., as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

## Article 81 (Disposition of Penalty Surcharges)

(1) If a manufacturer, a person who has obtained product approval, an importer of drugs, etc., a pharmacy founder or a distributor of drugs is to be subject to the disposition of business suspension under Article 76, the Commissioner of the Korea Food and Drug Administration, a Mayor/Do Governor or the head of a *Si/Gun/Gu* may impose a penalty surcharge not exceeding fifty million won in lieu of such disposition, as prescribed by Presidential Decree. In such cases, if a pharmacy founder who has been subject to the disposition of suspension of qualification as a pharmacist or oriental pharmacist under Article 79 (2) 2 comes to be subject to the disposition of business suspension under Article 76 (1) 5, the penalty surcharge in lieu thereof shall be imposed on less than three occasions. <Amended by Act No. 8643, Oct. 17, 2007>

(2) The amount of penalty surcharges according to categories of offenses against which penalty surcharges referred to in paragraph (1) are imposed and the degree thereof, and other necessary matters shall be prescribed by Presidential Decree.

(3) When necessary for the collection of a penalty surcharge, the Commissioner of the Korea Food and Drug Administration, a Mayor/Do Governor or the head of a *Si/Gun/Gu*, may request the head of the competent tax office to provide taxation information by a paper stating the following matters:

1. Personal information of the relevant tax payer;
2. Purpose of use;
3. Data on sales on which the imposition of a penalty surcharge shall be based.

(4) If a person liable to pay a penalty surcharge pursuant to paragraph (1) fails to pay it by the deadline of payment, the Commissioner of the Korea Food and Drug Administration, a Mayor/Do Governor or the head of a *Si/Gun/Gu* shall cancel the disposition of imposition of a penalty surcharge pursuant to paragraph (1),

and shall render disposition of business suspension pursuant to Article 76 (1) or (2), or shall collect it in the same manner as dispositions of national taxes or local taxes in arrears, as prescribed by Presidential Decree: However, where it is impossible to render disposition of business suspension pursuant to Article 76 (1) or (2) due to closure, etc. pursuant to Article 40, it shall be collected in the same manner as dispositions of national taxes or local taxes in arrears.

(5) The amount collected as penalty surcharges under paragraphs (1) and (4) shall revert to the State or local government to which the collecting agency belongs.

## Article 82 (Fees)

A person who intends to apply for a license, approval, registration, report, recognition, designation, pre-examination, the provision of information on the distribution of pharmaceuticals or deliberation of advertisement, or who intends to determine standards of new products, apply for examinations or requests matters prescribed by Ordinance of the Minister of Health and Welfare, shall pay a fee, as determined by Ordinance of the Minister of Health and Welfare. The same shall also apply to the modification of a license, approval, registration, report, recognition or matters prescribed by Ordinance of the Minister of Health and Welfare. <Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

## CHAPTER VIII SUPPLEMENTARY PROVISIONS

## Article 83 (Subsidization from National Treasury)

As prescribed by Presidential Decree, the Minister of Health and Welfare and the Commissioner of the Korea Food and Drug Administration may subsidize research funds to the manufacturers of drugs, etc. who have contributed to exportation, or to the institutions, etc. that contribute to the national health by carrying out research projects on the safety of drugs, etc. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

## Article 84 (Delegation and Entrustment of Authority)

(1) As prescribed by Presidential Decree, the authority of the Minister of Health and Welfare and that of the Commissioner of the Korea Food and Drug Administration under this Act may be partially delegated to the Commissioner of the Korea Food



and Drug Administration, a Mayor/Do Governor, or the director of the Korea Centers for Disease Control and Prevention; the authority of the Commissioner of the Korea Food and Drug Administration and a Mayor/Do Governor, to the head of a *Si/Gun/Gu* or the head of a community health center; and the authority of the head of a *Si/Gun/Gu*, to the head of a community health center, respectively. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(2) The Minister of Health and Welfare and the Commissioner of the Korea Food and Drug Administration may entrust an organization prescribed in Article 67 with part of pharmaceutical affairs under this Act, as prescribed by Presidential Decree. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 85 (Special Cases concerning Animal Drugs, etc.)

(1) Drugs or quasi-drugs, the purpose of which is to be used exclusively for animals, under the jurisdiction of the Commissioner of the Korea Food and Drug Administration under this Act, shall be matters under the jurisdiction of the Minister for Food, Agriculture, Forestry and Fisheries, and “Commissioner of the Korea Food and Drug Administration” in the corresponding provisions of this Act shall be construed as “Minister for Food, Agriculture, Forestry and Fisheries”, and “Ordinance of the Ministry of Health and Welfare” shall be construed as “Ordinance of the Ministry for Food, Agriculture, Forestry and Fisheries”. In such cases, when the Minister for Food, Agriculture, Forestry and Fisheries issues Ordinance of the Ministry for Food, Agriculture, Forestry and Fisheries, he/she shall consult with the Commissioner of the Korea Food and Drug Administration. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(2) With respect to the drugs for animals used for the diagnosis and treatment or prevention of animals' diseases, and designated as ones that may stay in an animal's body and inflict harm on human health, the Minister for Food, Agriculture, Forestry and Fisheries may determine the standards for use of animal drugs, such as animals for which such drugs are used, direction, dosage, the period banning its use, etc. <Amended by Act No. 8852, Feb. 29, 2008>

(3) Any person who desires to use animal drugs, the usage standards of which are determined under paragraph (2), shall observe such standards: However, where he/she uses them pursuant to the diagnosis or prescription of a veterinarian or

a certified marine disease manager, he/she may choose not to observe such standards.

(4) Notwithstanding the provisions of Article 44, a person who has established a veterinary hospital as prescribed by the Veterinarians Act, may sell animal drugs used for the treatment of animals to any person who rears them, or may purchase drugs for the purpose of treating animals from any pharmacy founder under the proviso to Article 50 (2). In such cases, a person who has established a veterinary hospital shall prepare and retain sale and purchase records, as prescribed by Ordinance of the Ministry for Food, Agriculture, Forestry and Fisheries. <Amended by Act No. 8852, Feb. 29, 2008>

(5) Notwithstanding the provisions of Article 44, a person who has established a marine disease management office as prescribed by the Fish Farming Development Act may sell drugs used for the treatment of marine life to any person who cultivates such marine life.

Article 86 (Projects for Relief of Injury from Adverse Drug Reactions)

(1) An organization composed of manufacturers, persons who have obtained product approval or importers of drugs shall carry out research projects to relieve any injury caused by adverse drug reactions and support the improvement of safety of drugs and the development of new drugs. <Amended by Act No. 8643, Oct. 17, 2007>

(2) Manufacturers, persons who have obtained product approval or importers of drugs shall bear the expenses incurred in the projects referred to in paragraph (1). <Amended by Act No. 8643, Oct. 17, 2007>

(3) For the purposes of the projects referred to in paragraph (1), the Government may provide a subsidy within budgetary limits.

(4) Matters necessary for the projects referred to in paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

Article 87 (Prohibition of Leakage of Confidential Information)

(1) No pharmacist or oriental pharmacist shall leak another person's confidential information which he/she has become aware of while dispensing and selling drugs except as otherwise provided for in this Act or other Acts and subordinate statutes.

(2) No person who has become aware of confidential business information on business of a person who has obtained product approval under Article 47-2 (2), an importer

and a wholesaler, etc. of drugs shall divulge such confidential information or use such confidential information for any purpose, other than business purpose. <Newly Inserted by Act No. 8643, Oct. 17, 2007>

## Article 88 (Protection of Submitted Data)

(1) With respect to data furnished pursuant to the provisions of Articles 31, 31-2, 32 through 34, 35-2 or 42, the Commissioner of the Korea Food and Drug Administration shall, when a person who has furnished such data files a written request for its protection, not make such data public: However, where the Commissioner of the Korea Food and Drug Administration deems it necessary to disclose such data for public interest, he/she may disclose it.

(2) No person who has read or examined furnished data for which a written request is filed for its protection under paragraph (1) shall make public the details of such data that he/she has learned as a result of such reading and examination.

## Article 89 (Succession of Status, etc. of Manufacturers, etc.)

(1) When a manufacturer, a person who has obtained product approval, a person who has reported a contract manufacture, a distributor of drugs (excluding herb druggists) or a person designated as an inspection institution (hereafter referred to as “manufacturer, etc.” in this Article and Article 89-2) dies or transfers his/her business, or a merger of corporate manufacturers, etc. takes place, the successor, transferee, corporation surviving such merger or corporation incorporated by such merger shall succeed to the status of the manufacturer, etc.: However, the same shall not apply in cases where such transferee, corporation surviving the merger or corporation incorporated by the merger falls under any of the following subparagraphs: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 6, 2011>

1. In cases of a manufacturer of drugs, a person who has obtained product approval or a person who has reported a contract manufacture: Where it falls under any subparagraph of Article 31 (8);

2. In cases of wholesale business of drugs, etc.: Where it falls under any subparagraph of Article 46.

(2) Where a manufacturer, a person who has obtained product approval, a person who has reported a contract manufacture or an importer of drugs has transferred

his/her business related to drugs, for which product approval of manufacture and import is obtained or a report is filed under Article 31 (2) through (4) or Article 42 (1), a manufacturer, a person who has obtained product approval, a person who has reported a contract manufacture or an importer of drugs, to whom the relevant business is transferred, shall succeed to the status of a manufacturer, a person who has obtained product approval, a person who has reported a contract manufacture or an importer of drugs, for which product approval is obtained or a report is filed. <Amended by Act No. 10788, Jun. 6, 2011>

(3) Any person who has succeeded to the status of a manufacturer, etc. under paragraphs (1) and (2), shall report to the Commissioner of the Korea Food and Drug Administration within one month, as prescribed by Ordinance of the Ministry of Health and Welfare: However, any person who has succeeded to the status of a manufacturer, etc. under paragraph (1), falls under any of subparagraphs of paragraph (1), he/she shall transfer the relevant status to a third party within six months from the date on which the relevant transfer commences. <Amended by Act No. 10788, Jun. 6, 2011>

## Article 90 (Bounty)

A bounty may be paid to any person who has reported the violation of Article 23, 24 (1) and (2), 26 (1), 27 (1) and (3), or 50 (1) and (2) to any supervisory agency or any investigative agency, as prescribed by Presidential Decree.

## Article 91 (Establishment of the Korea Orphan Drug Center)

(1) The Korea Orphan Drug Center (hereinafter referred to as the “Center”) shall be established to furnish information on drugs which have the rare subject of their application and are required to be urgently imported because of the lack of their substitute drugs and other drugs used to treat rare diseases (hereinafter referred to as “rare drugs, etc.”), and to supply (including the duties of dispensing and dosage of drugs; hereinafter the same shall apply) such drugs.

(2) The Center shall be a corporation.

(3) The provisions governing juridical foundations under the Civil Act shall apply *mutatis mutandis* to the Center, except as otherwise provided for in this Act.

(4) Necessary matters concerning the operation, etc. of the Center established under

paragraph (1) shall be prescribed by Presidential Decree.

Article 92 (Projects of Center)

- (1) The Center shall conduct the following projects:
1. Gathering information on rare drugs, etc. and building a computer network;
  2. Supplying rare drugs, etc.; in such cases, the president of the Center shall install a dispensary in the Center, designate a pharmacist from among the staff of the Center and have him/her take charge of the business;
  3. Other projects related to rare drugs, etc., which are approved by the Commissioner of the Korea Food and Drug Administration.
- (2) Where the Commissioner of the Korea Food and Drug Administration deems it necessary for the Center to perform the projects specified in paragraph (1), he/she may provide the Center with financial assistance, etc.

## CHAPTER IX PENAL PROVISIONS

Article 93 (Penal Provisions)

- (1) A person who falls under any of the following subparagraphs shall be punished by imprisonment for not more than five years, or by a fine not exceeding twenty million won: <Amended by Act No. 8643, Oct. 17, 2007>
1. A person who lends his/her license to another person, in violation of Article 6 (3);
  2. A person who establishes a pharmacy, in violation of Article 20 (1);
  3. A person who violates Article 23 (1);
  4. A person who fails to obtain approval or to report in violation of Article 31 (1) through (4);
  5. A person who fails to obtain approval, to report, to obtain approval for alteration, or to report alteration, in violation of Article 42 (1);
  6. A person who violates Article 43;
  7. A person who violates Article 44 (1);
  8. A person who sells drugs without obtaining approval pursuant to Article 44 (2) 2;

9. A person who violates Article 53 (1);
  10. A person who violates Article 61 (including cases applicable *mutatis mutandis* in Article 66).
- (2) As for the punishment referred to in paragraph (1), imprisonment and fines may be imposed concurrently.

Article 94 (Penal Provisions)

- (1) A person who falls under any of the following subparagraphs shall be punished by imprisonment for not more than three years, or by a fine not exceeding ten million won: However, any person who has violated Article 87 (1) may be charged only when an accusation is filed against him/her: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011>
1. A person who violates Article 3 (3) or 4 (3);
  2. A person who commits an act of collusion, in violation of Article 24 (2);
  3. A person who violates Article 34 (1), (2), (4) and (5);
  4. A person who violates Article 37 (3) (including cases applicable *mutatis mutandis* in Article 42 (4));
  5. A person who violates Article 45 (5);
  6. A person who sells drugs after breaking the seal of a container or package, in violation of the main sentence of Article 48;
  7. A person who sells, stores or displays drugs, in violation of Article 49;
  8. A person who violates Article 50 (1);
  9. A person who sells, manufactures, imports, stores or displays drugs, in violation of Article 62 (including cases applicable *mutatis mutandis* in Article 66);
  10. A person who refuses an order to manufacture drugs or an order to start work without justifiable grounds, in violation of Article 70 (2);
  11. A person who violates an order pursuant to Article 71 (1) and (2), or refuses, obstructs or evades the recall and scrapping of products carried out by the relevant public official pursuant to paragraph (3) of the same Article, and other necessary disposition;
  12. A person who violates Article 87 or 88 (2).
- (2) As for the punishment referred to in paragraph (1), imprisonment and fines

may be imposed concurrently.

Article 95 (Penal Provisions)

(1) A person who falls under any of the following subparagraphs shall be punished by imprisonment for not more than one year, or by a fine not exceeding three million won: <Amended by Act No. 8558, Jul. 27, 2007; Act No. 8643, Oct. 17, 2007; Act No. 10324, May 27, 2010; Act No. 10788, Jun. 7, 2011>

1. A person who fails to make a registration of establishment, in violation of Article 20 (2);
2. A person who violates Article 21 (1) and (2);
3. A person who violates Article 23 (2), (3), (4), (6) and (7);
4. A person who refuses to dispense drugs without justifiable grounds, in violation of Article 24 (1);
5. A person who dispenses drugs, in violation of Article 26 (1);
6. A person who violates Article 27 (1), (3) and (4);
7. A person who fails to perform affairs of safety control, in violation of Article 36 (including cases applicable *mutatis mutandis* in Article 42 (4)), 37 (2) (including cases applicable *mutatis mutandis* in Article 42 (4)) or 37-3 (1) (including cases applicable *mutatis mutandis* in Article 42 (4));
8. A person who violates Article 47 (1);
9. A person who sells prescription drugs, in violation of Article 50 (2);
10. A person who violates Article 60, 64 (1) or 68.

(2) As for the punishment referred to in paragraph (1), imprisonment and fines may be imposed concurrently.

Article 96 (Penal Provisions)

A person who falls under any of the following subparagraphs shall be punished by a fine not exceeding two million won: However, any person who has violated Article 30 (2) may be charged only when an accusation is filed against him/her: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011>

1. A person who violates Article 24 (3);
2. A person who violates Article 28, 29 or 30 (1) and (2);
3. A person who violates Article 37 (1), 37-3 (2) or 38 (1);
4. A person who violates Article 56 (1), 57, 58, 63 (including cases applicable

*mutatis mutandis* in Article 66), or 65 (1);

5. A person who refuses, obstructs or evades inspection, inquiry, collection, etc. by the competent public official pursuant to Article 69 (1);
6. A person who violates an order of report, announcement, inspection, repair, alteration, etc. pursuant to Articles 69 (1) and 72 through 75.

Article 97 (Joint Penal Provisions)

Where a representative of a corporation, or an agent, employee or other servant of the corporation or an individual commits an offence under Articles 93, 94, 94-2, 95, 95-2 and 96 in connection with the business of the corporation or the individual, in addition to the punishment of such offender, the corporation or the individual shall be punished by a fine under each relevant Article: *Provided*, That where such corporation or individual has not been negligent in giving due attention and supervision concerning the relevant duties to prevent such violation, this shall not apply.

Article 98 (Fines for Negligence)

(1) A person who falls under any of the following subparagraphs, shall be punished by a fine for negligence not exceeding one million won: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011>

1. A person who fails to make a report of a pharmacist or oriental pharmacist, in violation of Article 7;
2. A person who fails to receive training and education prescribed in Article 15;
3. A person who fails to observe the matters necessary for the management of a pharmacy, in violation of Article 21 (3);
4. A person who fails to report the discontinuance of business, etc., in violation of Article 22 or 40;
5. A person who fails to report the actual results of production or actual imports, etc. of drugs, etc., in violation of Article 38 (2) (including cases applicable *mutatis mutandis* in Article 42 (4));
6. A person who fails to report or falsely reports, in violation of the latter part of Article 39 (1);
7. A person who fails to report the preparation, etc. of pharmacy medication or dispensary medication in violation of Article 41 (1);

- 7-2. A person who fails to submit the details of supply of drugs, in violation of Article 47-2 (2);
8. A person who fails to report, in violation of Article 69 (1);
9. A person who fails to renew a certificate of license, approval or registration, in violation of Article 80;
10. A person who fails to observe the standards for use of animal drugs, in violation of Article 85 (3).
- (2) Fines for negligence referred to in paragraph (1) shall be imposed and collected by the Minister of Health and Welfare, the Commissioner of the Korea Food and Drug Administration, Mayors/*Do* Governors or the heads of *Sis/Guns/Gus*, as prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011>*
- (3) Deleted. *<by Act No. 10788, Jun. 7, 2011>*
- (4) Deleted. *<by Act No. 10788, Jun. 7, 2011>*
- (5) Deleted. *<by Act No. 10788, Jun. 7, 2011>*

## ADDENDA

## Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation: However, the amended provisions of Article 81 shall enter into force on July 4, 2007.

## Article 2 (Transitional Measures concerning Enforcement Date)

The former provisions of Article 71-3 that corresponds to the amended provisions of Article 81 shall apply until the latter enters into force pursuant to the proviso to Article 1 of Addenda.

## Article 3 (Applicability to Disposition of Imposition of Penalty Surcharge)

The amended provisions of Article 81 (4) shall begin to apply to a person who receives disposition of a penalty surcharge for the first time after July 4, 2007, which is the enforcement date of the partially amended Pharmaceutical Affairs Act (Act No. 8201).

## Article 4 (Transitional Measures concerning Drugs, etc. for Family Planning)

The amended provisions of Articles 44, 50 and 68 (4) shall not apply to products

selected by the Minister of Health and Welfare from among drugs for family planning. And notwithstanding the amended provisions of Articles 44 and 50, those designated by the Minister of Health and Welfare may be allowed to present or sell only the products designated by the Minister of Health and Welfare to end users, as stipulated by Ordinance of the Ministry of Health and Welfare, regarding the presentation and sale of drugs in trains, airplanes or other places designated by the Minister of Health and Welfare.

## Article 5 (Transitional Measures concerning Druggists, etc.)

Druggists (referring to the former drug dealers) and drug sellers who have obtained approval pursuant to the former Act and subordinate statutes as of January 13, 1971, the enforcement date of the amended Pharmaceutical Act (Act No. 2279), shall be governed by the former Act and subordinate statutes.

## Article 6 (Transitional Measures concerning Herb Druggists)

Any person who has been granted the approval of herb dealer as of January 13, 1971, the enforcement date of the amended Pharmaceutical Affairs Act (Act No. 2279), shall be deemed a herb druggist pursuant to this Act.

## Article 7 (Transitional Measures concerning Permitted Area of Herb Dealers)

Those who have left the permitted area due to war or other natural calamities from among herb dealers as of January 13, 1971, the enforcement date of the amended Pharmaceutical Affairs Act (Act No. 2279) and those who have left the permitted area before March 3, 1967, the enforcement date of the amended Pharmaceutical Affairs Act (Act No. 1910), may make the place of residence as the permitted area only if they obtain approval from the Seoul Special Metropolitan City Mayor, Busan Metropolitan City Mayor or *Do* Governor who has the jurisdiction of the place of residence concerned.

## Article 8 (Transitional Measures concerning Dispensing by Oriental Pharmacists and Veterinarians)

Where an oriental pharmacist dispenses herbal materials and herbal medicinal products in person which he/she uses for treatment, or a veterinarian prepares animal drugs in person which he/she uses for treatment, he/she may dispense drugs notwithstanding the amended provisions of Article 23 (1) and (2).

## Article 9 (Transitional Measures concerning Dispensing Herbal Medicines by Pharmacist)

Those who fall under any of the following subparagraphs may dispense herbal medicines by applying *mutatis mutandis* the amended provisions of Article 23 (6), notwithstanding the amended provisions of Article 23 (1):

1. A person who has a pharmacist license or who has not obtained a pharmacist license after graduating from a college majoring in pharmacology as at the time the amended Pharmaceutical Affairs Act (Act No. 4731) enters into force, who has passed the herbal medicine dispensing examination prescribed by Presidential Decree within two years from the date of enforcement of the same Act: However, the herbal medicine dispensing examination shall be taken after obtaining a pharmacist license;
2. A person who was attending a college majoring in pharmacology as at the time the amended Pharmaceutical Affairs Act (Act No. 4731) enters into force, who completed the herb related course stipulated by Ordinance of the Ministry of Health and Welfare and has succeeded in the herbal medicine dispensing examination prescribed by Presidential Decree within two years after the graduation: However, the herbal medicine dispensing examination shall be taken after obtaining a pharmacist license.

## Article 10 (Transitional Measures concerning Sale of Prescription Drugs by Druggists)

No druggists in operation as of July 1, 2000, which is the enforcement date of the amended Pharmaceutical Affairs Act (Act No. 6153) shall sell prescription drugs in an area, other than the area designated by the Minister of Health and Welfare, pursuant to the amended provisions of Article 23 (5) as an area where there is no medical institution or pharmacy.

## Article 11 (Transitional Measures concerning Substitute Dispensing)

The amended provisions of Article 27 shall enter into force 30 days after the list of local prescription drugs or list of prescription drugs by each medical institution has been supplied (where the list of prescription drugs has been coordinated pursuant to Article 25 (4), the date of such coordination) pursuant to Article 25 (2) to the relevant *Si/Gun/Gu* branch of the Pharmaceutical Association by a branch of the Medical Association, etc.

## Article 12 (Transitional Measures concerning the Korea Orphan Drug Center)

The Korea Orphan Drug Center, a juridical foundation founded pursuant to Article 32 of the Civil Act at the time of August 14, 2001, which is the enforcement date of the amended Pharmaceutical Affairs Act (Act No. 6511), shall be deemed the Korea Orphan Drug Center established pursuant to the amended provisions of Article 91.

## Article 13 (Special Examples concerning Granting Oriental Pharmacist's License)

Those who have completed 95 credits of the herb related subjects stipulated in Article 3-2 of the amended Enforcement Decree of the Pharmaceutical Affairs Act (Presidential Decree No. 14319) pursuant to the commission of Article 3-2 (2) of the amended Pharmaceutical Affairs Act (Act No. 7376) in a college and have succeeded in the national examination for oriental pharmacists from among those falling under any of the following subparagraphs shall be granted an oriental pharmacist's license, notwithstanding the amended provisions of Article 4 (2):

1. Those who have been attending a college majoring in pharmacology (limited to a department other than the herbal medicine department) as of March 6, 1997, who entered the college before 1996 school year;
2. Those who have graduated from a college majoring in pharmacology as of March 6, 1997;
3. Those who were attending a college, other than a college majoring in pharmacology as of March 6, 1997, and entered the college before 1996, and who have finished a college, other than a college majoring in pharmacology.

## Article 14 (Transitional Measures concerning Person who Received Bachelor's Degree in Pharmacology)

Those who have completed the herb course and have obtained a bachelor's degree in pharmacology as at the time the amended Pharmaceutical Affairs Act (Act No. 7635) enters into force shall be deemed those who have obtained a bachelor's degree in herb pursuant to the amended provisions of Article 4.

## Article 15 (Transitional Measures concerning Qualification for Applying for National Pharmacist's Examination and National Oriental Pharmacist's Examination)

Those who have the qualification for applying for the national pharmacist's examina-

tion or national oriental pharmacist's examination pursuant to the former provisions as at the time this Act enters into force shall be deemed to have the qualification for application pursuant to this Act.

Article 16 (Transitional Measures concerning the Korean Pharmaceutical Association, etc.)

The Korean Pharmaceutical Association, the Association of Korea Oriental Pharmacy, and chapters or branches thereof which all are established under the former provisions as at the time this Act enters into force, shall be deemed to have been established and set up pursuant to this Act.

Article 17 (Transitional Measures concerning Licenses)

Any person who has received a pharmacist's license or oriental pharmacist's license pursuant to the former provisions as at the time this Act enters into force shall be deemed to have received a license pursuant to this Act.

Article 18 (Transitional Measures concerning Disposition, such as Approval)

Where approval has been obtained from the Minister of Health and Welfare, the Commissioner of the Korea Food and Drug Administration, a Mayor/Do Governor or the head of a *Si/Gun/Gu*, or registration or report is made, or application for approval, registration, etc. is made to them as at the time this Act enters into force, it shall be deemed to have been obtained or made pursuant to this Act.

Article 19 (General Transitional Measures concerning Disposition, etc.)

Acts committed by or against administrative agencies pursuant to the former provisions as at the time this Act enters into force shall be deemed the acts committed by or against administrative agencies pursuant to this Act.

Article 20 (Transitional Measures concerning Penal Provisions and Fines for Negligence)

When applying penal provisions or provisions of fines for negligence to an act committed before this Act enters into force, the former provisions shall govern.

Article 21 Omitted.

Article 22 (Relationship with other Acts and Subordinate Statutes)

Where the former Pharmaceutical Affairs Act or a provision thereof is cited in other Act and subordinate statutes as at the time this Act enters into force, this Act or the corresponding provision in this Act shall be deemed to have been cited in place of the former provision if there exists a provision corresponding thereto

in this Act.

ADDENDA <Act No. 8558, Jul. 27, 2007>

(1) (Enforcement Date) This Act shall enter into force six months after the date of its promulgation.

(2) (Applicability concerning Confirmation of Suspect Matters of Prescription) The amended provisions of Article 26 (2) concerning confirmation of suspect matters of a prescription shall apply beginning from the first prescription written after this Act enters into force.

ADDENDA <Act No. 8643, Oct. 17, 2007>

(1) (Enforcement Date) This Act shall enter into force six months after the date of its promulgation: However, matters concerning the Korea Pharmaceutical Information Service shall enter into force one year after the date of its promulgation.

(2) (Transitional Measures concerning Notification, Disposition, Orders and On-going Activities) Notification, disposition, orders and other acts of administrative agencies or various applications, reports and other acts against administrative agencies under the former Pharmaceutical Affairs Act as at the time this Act enters into force shall be deemed acts by or against administrative agencies under this Act corresponding thereto.

(3) (Transitional Measures concerning Penal Provisions) The former Pharmaceutical Affairs Act shall apply to penal provisions or fines for negligence concerning violation of the former Pharmaceutical Affairs Act as at the time this Act enters into force.

ADDENDA <Act No. 8723, Dec. 21, 2007>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation.

Articles 2 through 5 Omitted.

ADDENDA <Act No. 8728, Dec. 21, 2007>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.

Articles 2 through 6 Omitted.

ADDENDA <Act No. 8852, Feb. 29, 2008>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 through 7 Omitted.

ADDENDUM <Act No. 9123, Jun. 13, 2008>

This Act shall enter into force six months after the date of its promulgation.

ADDENDA <Act No. 9819, Nov. 2, 2009>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation.

Articles 2 through 6 Omitted.

ADDENDA <Act No. 9847, Dec. 29, 2009>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.

Articles 2 through 22 Omitted.

ADDENDA <Act No. 9932, Jan. 18, 2010>

Article 1 (Enforcement Date)

This Act shall enter into force two months after the date of its promulgation. (Proviso Omitted.)

Articles 2 through 5 Omitted.

ADDENDUM <Act No. 10324, May 27, 2010>

This Act shall enter into force six months after the date of its promulgation.