PHARMACEUTICAL AFFAIRS ACT

Wholly Amended by Act No. 8365, Apr. 11, 2007
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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
Act No. 10512, Mar. 30, 2011
Act No. 10788, jun. 7, 2011
Act No. 10888, Jul. 21, 2011
Act No. 11118, Dec. 2, 2011
Act No. 11141, Dec. 31, 2011
Act No. 11251, Feb. 1, 2012
Act No. 11421, May 14, 2012
Act No. 11690, Mar. 23, 2013
Act No. 11985, Jul. 30, 2013
Act No. 11998, Aug. 6, 2013
Act No. 12074, Aug. 13, 2013
Act No. 12450, Mar. 18, 2014
Act No. 13114, Jan. 28, 2015
Act No. 13219, Mar. 13, 2015
Act No. 13320, May 18, 2015
Act No. 13367, jun. 22, 2015
Act No. 13425, Jul. 24, 2015
Act No. 13655, Dec. 29, 2015
Act No. 14084, Mar. 22, 2016
Act No. 14170, May 29, 2016

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Article 1 (Purpose)

The purpose of this Act is to prescribe matters necessary to deal with pharmaceutical affairs smoothly, thereby contributing to the improvement of the 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; Act No. 11690, Mar. 23, 2013; Act No. 12450, Mar. 18, 2014; Act No. 14328, Dec. 2, 2016>*

1. The term "pharmaceutical affairs" means the manufacture, dispensing, evaluation, safekeeping, importation, and sale (including presentation; hereinafter the same shall apply) of drugs and quasi-drugs, and other matters related to pharmaceutical technology;

2. The term "pharmacist" means a person who takes charge of matters concerning pharmaceutical affairs (including those concerning herb medication), other than those concerning herb drugs; the term "oriental medicine pharmacist" means a person who takes charge of matters concerning pharmaceutical affairs related to herb drugs and preparation thereof; 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 oriental medicine pharmacist dispenses drugs *[including pharmacy medication] for the purpose of presentation (including a place required for distribution business where the founder of a pharmacy engages in drug distribution business at the same time): Provided, That dispensaries of medical institutions shall be excluded herefrom;*

4. The term "drug" means any of the following:

(a) Those, other than quasi-drugs, among the articles listed in the Korean Pharmacopoeia;

(b) Articles, other than appliances, machinery or equipment, used for the purposes of diagnosis, medical care, alleviation, treatment or prevention of diseases of human beings or animals;

(c) Articles, 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 "herb" means raw drugs picked from animals, plants, or minerals, and dried, cut, or refined without changing the original forms in most cases;

6. The term "herb medication" means any drug made by mixing herbs according to the principle of oriental medicine;

7. The term "quasi-drug" means any of the following articles designated by the Minister of Food and Drug Safety (excluding articles which shall be used for the purposes prescribed in 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 articles that have insignificant influences on or do not directly act upon human bodies;

(c) Preparations used for sterilization, insecticide, and uses similar thereto for the purpose of preventing infectious 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 Minister of Food and Drug Safety;

9. The term "over-the-counter drug" means any of the following drugs, which meets the standards prescribed and announced by the Minister of Food and Drug Safety, following consultations with the Minister of Health and Welfare:

(a) A drug, the misuse or 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 physician or a dentist;

(b) A drug that may be used to cure a disease without a physician's or dentist's professional knowledge;

(c) A drug that has a relatively small side effect on human bodies in light of their 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 dispensing drugs for the purposes of treatment, prevention, etc. of a certain disease for a specific individual in accordance with the specific directions by mixing at least two drugs or by dividing one kind of drug into certain dosages according to a specific prescription;

12. The term "medication counselling" means any of the following:

(a) Providing information on the names, directions for use and dosage, efficacy and effects, storage methods, side effects, interactions, properties, conditions, 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 manufacturing business" means the business of manufacturing and marketing drugs without owning manufacturing facilities by entrusting a drug manufacturer with the manufacture and marketing of drugs approved by the Minister of Food and Drug Safety;

15. The term "clinical trial" means a test that checks pharmacodynamic, pharmacokinetic, pharmacological, and clinical effects of drugs, etc. and investigates adverse reactions occurring on human bodies in order to prove the safety and efficacy of the relevant drugs, etc.;

16. The term "non-clinical trial" means a test conducted by using animals, plants, microorganism, a physical or chemical medium, or the composite thereof under the same conditions as those in 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 test" means a medical examination using a living body administered to prove biological equivalence, which shows that bioavailability of two pharmaceutical preparations containing the same major components is statistically equivalent;

18. The term "orphan drug" means a drug under subparagraph 4 falling under any of the following, designated by the Minister of Food and Drug Safety:

(a) A drug used for the purposes of diagnosis or treatment of rare diseases under subparagraph 1 of Article 2 of the Rare Disease Management Act;

(b) A drug with rare subject of application, whose alternative drug does not exist or whose safety or efficacy has been significantly improved compared to its alternative drug;

19. The term “national essential drug” means a drug essential for health and medical treatment, such as disease control, prevention of radiation disaster, etc., but whose stable supply is difficult only by the market function, and which is designated by the Minister of Health and Welfare and the Minister of Food and Drug Safety in consultation with the head of a relevant central administration agency.

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 prescribed in paragraph (1) shall be granted to any of the following persons: *<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 a 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 a national examination for pharmacist licenses.

(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 Medicine Pharmacists)

(1) Any person who desires to become an oriental medicine 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 medicine pharmacist prescribed in paragraph (1) shall be granted to a person who has graduated from herb pharmacy in a college, received a bachelor's degree in herb pharmacy, and passed a national examination for oriental medicine pharmacist licenses.

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

Article 5 (Grounds for Disqualification)

No license of a pharmacist or oriental medicine pharmacist shall be given to any of the following persons: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 11118, Dec. 2, 2011; Act No. 11251, Feb. 1, 2012; Act No. 12450, Mar. 18, 2014>*

1. A mental patient prescribed in subparagraph 1 of Article 3 of the Mental Health Act: Provided, That this shall not apply to a person who is recognized by a medical specialist to be suitable for taking charge of pharmaceutical affairs;
2. A person under adult guardianship or person under limited guardianship;
3. A person addicted to narcotics, marijuana, or psychotropic drugs;
4. A person who has been sentenced to imprisonment without prison labor or a heavier penalty on charges of violating the Pharmaceutical Affairs Act, the Narcotics Control Act, 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 the drug expenses by demanding the drug expenses by falsity; hereinafter the same shall apply) and other 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 for whom three years have not elapsed since his/her license was revoked by committing the crimes under Article 347 of the Criminal Act or for whom two years have not elapsed since his/her license was revoked by violating statutes relating to pharmaceutical affairs.

Article 6 (Issuance and Registration of Licenses)

(1) When the Minister of Health and Welfare issues a pharmacist's or oriental medicine pharmacist's license, he/she shall register matters relating to the license in the relevant registry and issue the relevant license. *<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 a third party.

(4) Matters necessary for registration of a pharmacist's or oriental medicine 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 Medicine Pharmacists)

Each pharmacist or oriental medicine pharmacist shall file a report on matters with 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; Act No. 10788, Jun. 7, 2011>*

Article 8 (National Examinations for Pharmacist Licenses or Oriental Medicine Pharmacist Licenses)

(1) National examinations for pharmacist licenses or oriental medicine pharmacist licenses shall be administered 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 the Korea Health Personnel Licensing Examination Institute established under the Korea Health Personnel Licensing Examination Institute Act to administer national examinations for pharmacist licenses or oriental medicine pharmacist licenses referred to in paragraph (1), as prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 13367, Jun. 22, 2015>*

(3) Where the Minister of Health and Welfare commissions the Korea Health Personnel Licensing Examination Institute to administer national examinations pursuant to paragraph (2), he/she may subsidize necessary expenses. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 13367, Jun. 22, 2015>*

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

Article 9 (Restrictions on Application for Examination)

No person falling under subparagraphs 1 through 3 of Article 5 shall apply for the national examination for pharmacist licenses or oriental medicine pharmacist licenses.

Article 10 (Cheating of Examinees)

(1) Each person, who has cheated in a national examination for pharmacist licenses or oriental medicine pharmacist licenses, 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 disqualify persons falling under paragraph (1) from applying for a national examination for pharmacist licenses or oriental medicine pharmacist licenses, for two years. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

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 the pharmacists' interests and elevate their quality.

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

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

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

(5) The Pharmaceutical Association shall establish the Ethics Committee in order to deliberate on and resolve requests for the disposition of qualification suspension under Article 79-2. *<Newly Inserted by Act No. 10788, Jun. 7, 2011>*

(6) Matters necessary for the organization and operation of the Ethics Committee shall be prescribed by Presidential Decree. *<Newly Inserted by Act No. 10788, Jun. 7, 2011>*

Article 12 (Oriental Pharmacy Association)

(1) Oriental medicine 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 herb and herb medication, establish oriental medicine pharmacists' ethics, promote the oriental medicine pharmacists' interests and elevate their quality.

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

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

(4) The provisions of the Civil Act concerning a corporate juridical person, in addition to those as provided for in this Act, shall apply mutatis mutandis to the Oriental Pharmacy Association.

(5) The Oriental Pharmacy Association shall establish the Ethics Committee in order to deliberate on and resolve requests for the disposition of qualification suspension under Article 79-2. *<Newly Inserted by Act No. 10788, Jun. 7, 2011>*

(6) Matters necessary for the organization and operation, etc. of the Ethics Committee shall be prescribed by Presidential Decree. *<Newly Inserted by Act No. 10788, Jun. 7, 2011>*

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 the Pharmaceutical Association and the Oriental Pharmacy Association)

(1) The Pharmaceutical Association or the Oriental Pharmacy Association shall establish its chapters in the Special Metropolitan City, Metropolitan Cities, Special Self-Governing City, Dos and Special Self-Governing Province (hereinafter referred to as "City/Do"), and may establish branches in the Gus of the Special Metropolitan City and Metropolitan Cities, Sis (referring to an administrative-Si in cases of the Special Self-Governing Province; hereinafter the same shall apply) and Guns. *<Amended by Act No. 10788, Jun. 7, 2011; Act No. 13114, Jan. 28, 2015>*

(2) When the Pharmaceutical Association or the Oriental Pharmacy Association has established its chapters and branches, it shall, without delay, file a report thereon with the Special Metropolitan City Mayor, Metropolitan City Mayors, Special Self-Governing City Mayor, Do Governors, or Special Self-Governing Province Governor. (hereinafter referred to as "Mayor/Do Governor"). *<Amended by Act No. 13114, Jan. 28, 2015>*

Article 15 (Training and Education)

(1) The Minister of Health and Welfare may order pharmacists and oriental medicine pharmacists to undergo training and education for the improvement of their quality. *<Amended by Act No. 8852, Feb. 29,*

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

(2) Matters necessary for 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 of the Minister of Health and Welfare concerning projects for the improvement of national public health, pharmaceutical affairs, and pharmacists' or oriental medicine 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 matters concerning pharmaceutical affairs and pharmacists' or oriental medicine 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 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 for pharmacists or oriental medicine pharmacists, investigation and research, he/she may fully or partially subsidize necessary expenses. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 18 (Central Pharmaceutical Affairs Council)

(1) A Central Pharmaceutical Affairs Council shall be established under the control of the Minister of Food and Drug Safety in order to respond inquiries from the Minister of Health and Welfare and the Minister of Food and Drug Safety when requested. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

(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>*

Article 20 (Registration for Establishment of Pharmacies)

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

(2) Each person who intends to establish a pharmacy, shall file for 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 amendments to registered matters. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(3) Each person who intends to file for registration under paragraph (2), shall install necessary facilities in conformity with standards for facilities prescribed by Presidential Decree.

(4) The Mayor/Do Governor may formulate standards for registration for establishing a pharmacy, respectively by regulations of the relevant City/Do, as prescribed by Presidential Decree.

(5) In any of the following cases, the application for registration for establishment of a pharmacy shall be rejected:

1. Where a person whose registration for establishment of a pharmacy has been revoked pursuant to Article 76 intends to re-apply for registration before the lapse of six months;

2. Where a pharmacy is to be established in a place located within facilities or premises of a medical institution;

3. Where a pharmacy is established by dividing, altering, or repairing some 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.

(6) No person shall use the word "pharmacy" or similar unless he/she is registered for establishment of a pharmacy pursuant to paragraph (2). *<Newly Inserted by Act No. 12450, Mar. 18, 2014>*

Article 21 (Duties to Manage Pharmacies)

(1) A pharmacist or oriental medicine pharmacist may establish only one pharmacy.

(2) Each pharmacy founder shall manage his/her pharmacy in person: Provided, That where a pharmacy founder is unable to manage the pharmacy, he/she shall designate a pharmacist or a oriental medicine pharmacist who manages such pharmacy on his/her behalf.

(3) Each pharmacist or oriental medicine pharmacist who manages a pharmacy shall observe the following matters necessary for managing such pharmacy: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013; Act No. 13655, Dec. 29, 2015>*

1. He/she shall manage his/her pharmacy and drugs in a manner not to harm health and sanitation and not to reduce the efficacy of drugs;

2. He/she shall thoroughly oversee his/her employees in order to prevent any sanitary incident;

3. He/she shall keep any goods likely to incur any sanitary danger off from his/her pharmacy;

4. He/she shall take necessary safety measures where any side effect, etc. occurs in connection with the use of drugs, etc.;

5. He/she shall observe other matters which correspond to the matters referred to in subparagraphs 1 through 4 and are prescribed by Ordinance of the Ministry of Health and Welfare, following consultation with the Minister of Food and Drug Safety, as deemed necessary to manage the facilities and drugs of pharmacies in a manner not to cause any harm to health and sanitation;

6. He/she shall observe other matters which correspond to the matters referred to in subparagraphs 1 through 5 and are prescribed by Ordinance of the Ministry of Health and Welfare, following consultation with the Minister of Food and Drug Safety, as deemed necessary to manage the facilities and drugs of pharmacies in a manner not to harm health and sanitation.

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

Where a pharmacy founder discontinues business of his/her 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 pharmacy within seven days from the date of discontinuation, suspension or resumption, as prescribed by Ordinance of the Ministry of Health and Welfare: Provided, That the same shall not apply where the period of suspension of business is less than one month. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 23 (Dispensing Drugs)

(1) No person, other than pharmacists or oriental medicine pharmacists, may dispense drugs, and pharmacists or oriental medicine pharmacists shall dispense drugs within their licensed area: Provided, That university students majoring in pharmacy may dispense drugs to the extent 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) Each pharmacist or oriental medicine pharmacist shall dispense drugs at a pharmacy or a dispensary of a medical institution (including a dispensary installed in the Korea Orphan and Essential Drug Center pursuant to the latter part of Article 92 (1) 2): Provided, That this shall not apply where he/she has obtained approval from the head of the relevant Si/Gun/Gu. *<Amended by Act No. 14328, Dec. 2, 2016>*

(3) Each physician or dentist shall be entitled to prescribe prescription drugs and over-the-counter drugs, and each pharmacist shall be entitled to dispense prescription drugs and over-the-counter drugs according to the prescriptions issued by physicians or dentists: Provided, That a pharmacist may dispense drugs without prescriptions issued by a physician or dentist in any of the following cases: *<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 disaster relief because medical institutions become virtually nonexistent in times of a natural disaster;
3. Where he/she sells oral vaccines to prevent spread of an infectious disease after the Minister of Health and Welfare recognizes such infectious disease has broken out or is likely to break out widely;
4. Where he/she dispenses drugs for community service activities.

(4) Notwithstanding paragraph (1), a physician 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, 2009; Act No. 9847, Dec. 29, 2009; Act No. 9932, Jan. 18, 2010; Act No. 10512, Mar. 30, 2011; Act No. 11251, Feb. 1, 2012; Act No. 13425, Jul. 24, 2015; Act No. 14170, May 29, 2016>*

1. Where he/she dispenses drugs in an area where no pharmacy exists;
2. Where he/she dispenses drugs for disaster relief because pharmacies become virtually nonexistent in times of a natural disaster;
3. Where he/she dispenses drugs for an emergency patient or a mental patient suffering from schizophrenia, a manic-depressive insanity, etc. who is likely to harm himself/herself or third persons;
4. Where he/she dispenses drugs for an in-patient; a patient suffering from a Type 1 infectious disease under the Infectious Disease Control and Prevention Act; or a person admitted to a social welfare facility under the Social Welfare Services Act (where a person does not board and lodge in such social welfare 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 administers medication, including vaccines to prevent infectious diseases, drugs for medical examinations, and other drugs 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 performance of his/her duties (excluding ambulatory care services for residents within the jurisdiction of a public health center or a public health branch office designated by the Minister of Health and Welfare);

8. Where he/she dispenses drugs for veterans with disability ratings 1 through 3 under the Act on the Honorable Treatment and Support of Persons, etc. of Distinguished Services to the State and its Enforcement Decree; persons with disability ratings 1 through 4 among those wounded in the May 18 Democratization Movement under the Act on the Honorable Treatment of Persons of Distinguished Service to the May 18 Democratization Movement; persons with severe disabilities under the Act on Assistance, etc. to Patients from Actual or Potential Aftereffects of Defoliants and its Enforcement Decree; persons with disability ratings 1 and 2 under the Act on Welfare of Persons with Disabilities and its Enforcement Decree and disabled 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 soldiers in active service; conscripted policemen; and inmates of correctional institutions under the Administration and Treatment of Correctional Institution Inmates Act and the Act on the Execution of Criminal Penalties in the Armed Forces and the Treatment of Military Prison Inmates, protected juvenile accommodation facilities under the Act on the Treatment of Protected Juveniles, Etc., and internment facilities under the Immigration Act;

11. Where he/she administers medication of drugs for the treatment of tuberculosis under the Tuberculosis Prevention Act (limited to public health centers, public health branches, and hospitals affiliated to the Korean National Tuberculosis Association);

12. Where he/she dispenses drugs for community service activities;

13. Where he/she is prohibited from disclosing prescriptions for the sake of the confidentiality of information related to the national security;

14. Other cases prescribed by Presidential Decree.

(5) The scope of an 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) Each oriental medicine pharmacist shall dispense herb drugs according to the prescriptions issued by oriental medical doctors: Provided, That he/she may dispense herb drugs without prescriptions issued by oriental medical doctors, according to the category of herb drug prescriptions or by a dispensing method

determined by the Minister of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(7) Each pharmacist engaging in dispensing drugs at a dispensary of a medical institution, shall be prohibited from dispensing drugs for a patient to whom a prescription is issued under Article 18 of the Medical Service Act.

Article 23-2 (Checking Drug Information)

(1) Where a pharmacist dispenses a drug pursuant to Article 23 (3), he/she shall ascertain the following information (hereinafter referred to as "drug information") in advance:

1. Whether the ingredients of the drug are the same as those of the drug prescribed and administered to the patient;
2. Whether the drug contains the ingredients of drugs contraindicated in pregnancy, drugs with drug interactions and drugs with age limits which have been publicly announced by the Minister of Food and Drug Safety;
3. Other information prescribed by Ordinance of the Ministry of Health and Welfare.

(2) Notwithstanding paragraph (1), a pharmacist need not ascertain drug information where justifiable grounds exist.

(3) Methods and procedures for ascertaining drug information pursuant to paragraph (1), justifiable grounds specified in paragraph (2), etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 23-3 (Establishment and Operation of Information System for Safe Use of Drugs)

(1) The Minister of Health and Welfare may establish and operate an information system for safe use of drugs (hereinafter referred to as "information system") to support the check of drug information pursuant to Article 23-2 of this Act, and Article 18-2 of the Medical Service Act.

(2) The Minister of Health and Welfare may commission a specialized institution prescribed by Ordinance of the Ministry of Health and Welfare to operate the information system. In such cases, the Minister of Health and Welfare may support all or some of expenses incurred in operating the information system.

(3) The Minister of Health and Welfare or the head of the specialized institution commissioned under paragraph (2) may request the physicians, dentists, pharmacists, etc. to provide the information prescribed by Ordinance of the Ministry of Health and Welfare as necessary for operation of the information system (including sensitive information pursuant to Article 23 of the Personal Information Protection Act and personally identifiable information pursuant to Article 24 of the same Act; in such cases, the relevant information shall be protected pursuant to the Personal Information Protection Act), and handle such information. In such cases, the doctors, dentists, pharmacists, etc. in receipt of the request shall comply with such request, except for extenuating circumstances.

(4) The Minister of Health and Welfare may establish and operate an Operation Committee of the Information System for Safe Use of Drugs (hereafter referred to in this Article as "Operation Committee") for seamless operation of the information system referred to in paragraph (1).

(5) Matters necessary for establishment and operation of the information system referred to in paragraph (1), the commissioning referred to in paragraph (2), organization and management of the Operation Committee referred to in paragraph (4), etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 24 (Duties and Matters to be Observed)

(1) No pharmacist or oriental medicine pharmacist engaging in dispensing drugs at a pharmacy, shall refuse any request to dispense drugs, without just cause.

(2) Each 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 conduct:

1. A pharmacy founder wholly or partially exempting any person carrying a medical prescription issued by a specific medical institution from paying drug expenses;

2. A pharmacy founder 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. A pharmacy founder directing or inducing any person carrying its medical prescription to get drugs dispensed at a specific pharmacy (excluding the act of introducing the full names, locations, etc. of pharmacies in the relevant area at the request of any patient);

4. A physician or dentist repeatedly prescribing other drugs identical in composition to drugs that are included in the list of prescription drugs offered by the branches of the Medical Association or the branches of the Dental Association to the branches of the Pharmaceutical Association prescribed in 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 any of those referred to in subparagraphs 1 through 4, prescribed by Presidential Decree as having the potential for collusion.

(3) Where a pharmacist or oriental medicine pharmacist working at a dispensary of a medical institution prescribed in Article 23 (2) dispenses drugs, he/she shall observe matters prescribed by Ordinance of the Ministry of Health and Welfare, following consultation with the Minister of Food and Drug Safety. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

(4) Where a pharmacist dispenses drugs to a patient, he/she shall give the patient or his/her protector necessary oral or written medication counselling in which a direction for taking medicines (referring to a written direction or electronic document explaining the details of medication counselling in terminologies readily comprehended by the patient) is written. In such case, necessary matters, such as the directions for taking medicines, etc., shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 12450, Mar. 18, 2014>*

(5) The Minister of Health and Welfare may take necessary measures for pharmacists to conscientiously offer patients the medication counseling referred to in paragraph (4), by allowing them to dispense a proper number of medical prescriptions. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 25 (Preparation, etc. of 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 the "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, the items of which are appropriately selected from the list of prescription drugs of each medical institution pursuant to paragraph (1) and a list of prescription drugs of each medical institution which are selected from 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), inform pharmacy founders in the relevant area of such lists and require them to secure relevant drugs.

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

(5) Where the branch of the Medical Association, etc. intends to alter or add the list of prescription drugs referred to in paragraph (2), it shall inform the branch of the Pharmaceutical Association thereof 30 days in advance.

Article 26 (Modification and Revision of Prescriptions)

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

(2) Where a name, quantity, directions, dose, etc. of any of drugs stated in a prescription is suspected to fall under any of the following cases, a pharmacist or oriental medicine pharmacist shall not dispense the drug unless he/she has confirmed any suspicious matters with the physician, dentist, oriental medical doctor, or veterinarian who has issued the prescription, by telephone and fax or by telephone and e-mail: *<Amended by Act No. 8558, Jul. 27, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11141, Dec. 31, 2011; Act No. 11690, Mar. 23, 2013; Act No. 13655, Dec. 29, 2015>*

1. Where a drug, the marketing approval or notification of which is revoked by the Minister of Food and Drug Safety due to any defect in terms of safety and efficacy of the drug, is prescribed;

2. Where it is impracticable to confirm a product name of a drug or names of ingredient thereof;

3. Where a drug publicly announced by the Minister of Food and Drug Safety as drugs with drug interactions, or drugs with age limits in accordance with the criteria for medical care benefits prescribed by Ordinance of the Ministry of Health and Welfare pursuant to Article 41 (3) of the National Health Insurance Act, is prescribed.

(3) Methods and procedures for revising and modifying prescriptions under paragraph (1), or other detailed 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 27 (Dispensing Substitute Drugs)

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

(2) Notwithstanding paragraph (1), a pharmacist may dispense a substitute drug without obtaining prior consent of the physician or dentist who has issued the prescription slip where it falls under any of the following cases: *<Amended by Act No. 11690, Mar. 23, 2013>*

1. Where the pharmacist dispenses a substitute drug recognized by the Minister of Food and Drug Safety 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): Provided, That where the physician or dentist has indicated in the prescription slip that dispensing a substitute drug is not permissible, and has stated in detail the clinical reasons, etc. therefor, such substitute drug 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: Provided, That dispensing a substitute drug shall be limited only in cases where a substitute over-the-counter drug is dispensed in place of an over-the-counter drug and a substitute prescription drug is dispensed in place of a prescription drug;

3. Where the pharmacist dispenses a substitute drug, with the same ingredients, content, and dosage form as the drug stated in the prescription slip, which is included in the regional list of prescription drugs of the relevant pharmacy where a drug, which is stated in the prescription slip issued by a medical institution located in a region other than the Si/Gun/Gu in which the relevant pharmacy is located, is not included in the regional list of prescription drugs of the relevant pharmacy, and for which it is difficult to obtain prior consent of the physician or dentist who has issued the prescription slip due to any unavoidable reasons.

(3) Where a pharmacist dispenses a drug substitute for the drug prescribed in a prescription slip under paragraph (1) or (2), he/she shall notify the person carrying such prescription slip of the detail of such substitute drug that has been dispensed.

(4) Where a pharmacist dispenses a drug substitute for the drug prescribed in a prescription slip under paragraph (2), he/she shall notify the physician or dentist who has issued such prescription slip of the details of such substitute drug that has been dispensed within one day (three days if any unavoidable reasons exist) from the date of dispensing: Provided, That the same shall not apply where the pharmacist dispenses such substitute drug after obtaining prior consent of the physician or dentist who has issued the prescription slip thereof. *<Amended by Act No. 13655, Dec. 29, 2015>*

(5) Where any pharmacist dispenses a drug substitute for the drug prescribed in a prescription slip without prior consent of the physician or dentist who has issued such prescription slip, such physician 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 giving notification, 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 medicine pharmacist shall indicate the relevant patient's name, directions, and dosage 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 medicine 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)

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

Article 30 (Records of Dispensing)

(1) Where a pharmacist dispenses drugs (including where he/she dispenses drugs without a prescription in accordance with the proviso to Article 23 (3), and each subparagraph of the said Article; hereafter the same shall apply in this Article) at his/her pharmacy, he/she shall make records (or electronic records), including the personal information of a patient, date of dispensing, the names of drugs prescribed, and the days of taking drugs, details of dispensing, details of medication counselling and other matters prescribed by Ordinance of the Ministry of Health and Welfare, and preserve such records for five years. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10512, Mar. 30, 2011>*

(2) Any patient may file a request for a perusal of his/her records or issuance of a copy thereof with a pharmacist to verify the details of his/her records. In such cases, the pharmacist in receipt of such request shall not refuse it without just cause. *<Amended by Act No. 13655, Dec. 29, 2015>*

(3) No pharmacist shall allow any person other than a patient to verify the details of the patient's records, by allowing a perusal of such records or issuing the copy of such records: Provided, That he/she may allow any person other than a patient to verify the details of the patient's records, in any of the following

cases: *<Newly Inserted by Act No. 13655, Dec. 29, 2015>*

1. Where the spouse, a lineal ascendant or descendant, a sibling (limited to where the spouse, any of lineal ascendants or descendants, and any of lineal ascendants of the spouse, of a patient does not exist) of a patient, or a lineal ascendant of the spouse of a patient, files a request, by submitting the written consent of the patient himself/herself or a document, etc. certifying the relative relationship or by fulfilling the requirements prescribed by Ordinance of the Ministry of Health and Welfare;
2. Where a representative designated by a patient files a request, by submitting the written consent of the patient himself/herself or a document proving the right of representation or by fulfilling the requirements prescribed by Ordinance of the Ministry of Health and Welfare;
3. Where the legal representative (limited to a guardian referred to in Article 928 or 936 of the Civil Act) of a patient files a request, by submitting a document proving the right of representation or by fulfilling the requirements prescribed by Ordinance of the Ministry of Health and Welfare;
4. Where the spouse, a lineal ascendant or descendant, a sibling (limited to where the spouse, any of lineal ascendants or descendants, and any of lineal ascendants of the spouse, of a patient does not exist) of a patient, or a lineal ascendant of the spouse of a patient, files a request, by submitting a document, etc. certifying the relative relationship or by fulfilling the requirements prescribed by Ordinance of the Ministry of Health and Welfare, since it is impracticable to obtain consent from the patient due to a death or unconsciousness of the patient;
5. Where records of dispensing are provided to the National Health Insurance Service or the Health Insurance Review and Assessment Service pursuant to Articles 14, 47, 48 and 63 of the National Health Insurance Act for the review and payment of medical care costs, verification of entitlement to medical care benefits, follow-up management, evaluation of the reasonableness of medical care benefits, adjusted payment of medical are benefits, etc.;
6. Where records of dispensing are provided to social security agencies (Si, Gun or Gu), the National Health Insurance Service, or the Health Insurance Review and Assessment Service pursuant to Articles 5, 11, 11-3 and 33 of the Medical Care Assistance Act for the verification of eligible recipients of medical aids, the review, payment, follow-up management, etc. of medical aid costs, or other medical aid services;
7. Where it falls under Article 106, 215 or 218 of the Criminal Procedure Act;
8. Where a court issues an order to submit records of dispensing pursuant to Article 347 of the Civil Procedure Act.

Article 31 (Permission for Manufacturing Business, etc.)

(1) Each person who intends to manufacture drugs for business purposes, shall obtain permission from the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister, after obtaining necessary facilities meeting standards for facilities prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

(2) Each manufacturer prescribed in paragraph (1) who intends to market drugs manufactured (including cases of entrusting another manufacturer with manufacture), shall obtain marketing approval for a drug he/she intends to manufacture and market for each product (hereinafter referred to as "marketing approval") from the Minister of Food and Drug Safety or file notification of a drug he/she intends to manufacture and market for each product (hereinafter referred to as "marketing notification"), as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

(3) Where a person, other than a manufacturer prescribed in paragraph (1), intends to entrust a manufacturer with the manufacture and marketing of any of the following drugs, he/she shall files a report on contract-manufacturing and marketing business with the Minister of Food and Drug Safety and obtain marketing approval for each product, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

1. A drug, the clinical trials of which have been conducted after obtaining approval for a protocol of clinical trials pursuant to Article 34 (1);
2. A biological preparation, recombinant DNA drug, cell culture technology-derived products, cellular therapy products, gene therapy products, and similar drugs for which clinical trials prescribed by Ordinance of the Prime Minister have been conducted in a foreign country in addition to the clinical trials prescribed in subparagraph 1;

(4) Each person who intends to manufacture quasi-drugs for business purposes shall file a report on manufacturing business with the Minister of Food and Drug Safety after obtaining necessary facilities meeting standards for facilities prescribed by Presidential Decree, and obtain marketing approval or file marketing notification. *<Amended by Act No. 11690, Mar. 23, 2013>*

(5) Each person who has obtained marketing approval or filed marketing notification pursuant to paragraphs (2) and (3) (hereinafter referred to as "person holding marketing approval") may establish a business office, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

(6) Notwithstanding paragraphs (1) through (4), permission for manufacturing business, marketing approval, or marketing notification may be omitted with regard to drugs or quasi-drugs prescribed by Ordinance of the Prime Minister, such as drugs for clinical trials prescribed in Article 34 (hereinafter referred to as "drugs, etc."). *<Newly Inserted by Act. No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013>*

(7) Notwithstanding paragraphs (2) through (4), a product or an item, in which a drug, etc., and a medical device are combined or complexly made and which has been licensed or notified pursuant to the Medical Devices Act because its major function is that of a medial device, shall be deemed approved or notified pursuant to paragraphs (2) through (4). *<Newly Inserted by Act. No. 10512, Mar. 30, 2011>*

(8) None of the following persons shall obtain permission and file a report on the business of manufacturing drugs, etc. or the business of contract manufacturing: *<Amended by Act. No. 10512, Mar. 30, 2011>*

1. A person falling under any subparagraph of Article 5;

2. A person in whose case one year has not passed since the revocation of permission for manufacturing business or the closure of a contract manufacturing business office or a factory pursuant to Article 76;

3. A person declared bankrupt and not reinstated.

(9) Where a person intends to change any of the matters prescribed by Ordinance of the Prime Minister among matters approved or notified under paragraphs (1) through (4), he/she shall obtain revised marketing approval, or file revised marketing notification, as prescribed by Ordinance of the Prime Minister. *<Amended by Act. No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013>*

(10) If an item covered by, or subject to, marketing approval or notification pursuant to paragraphs (2) and (3), is a new drug or a drug designated by the Minister of Food and Drug Safety, the following documents related to its safety and efficacy shall be submitted, as prescribed by Ordinance of the Prime Minister: Provided, That subparagraph 2 shall be excluded herefrom, where drug substances have been registered pursuant to Article 31-2: *<Amended by Act. No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013>*

1. Test results and data related thereto;

2. Data on drug substances;

3. Relevant documents;

4. Other necessary data.

(11) When granting permission for, or reporting on, the business of manufacturing drugs, etc. and contract manufacturing business, or granting approval, or filing notification, for manufacturing or marketing products under paragraphs (1) through (4) and (9), matters necessary for the subject matter of permission, reporting, approval or notification, standards therefor, conditions therefor, management thereof, etc., shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act. No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013>*

Article 31-2 (Registration, etc. of Drug Substances)

(1) A person who intends to manufacture and sell a drug substance of a new drug or a drug substance which is determined and publicly notified by the Minister of Food and Drug Safety may file a registration for the matters prescribed by Ordinance of the Prime Minister, such as its components, name and manufacturing method, with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

(2) The Minister of Food and Drug Safety shall examine whether the matters of registration under paragraph (1) satisfy the criteria prescribed by Ordinance of the Prime Minister, inform the relevant applicant of the examination results, record the details of examination in the drug substance register, and keep the register. In such cases, he/she shall publicly notify the matters prescribed by Ordinance of the Prime Minister, such as the components and manufacturer of the relevant drug substance. *<Amended by Act No. 11690, Mar. 23, 2013>*

(3) A person who intends to change important matters prescribed by Ordinance of the Prime Minister among the matters registered pursuant to paragraphs (1) and (2), shall file a registration for such change

with the Minister of Food and Drug Safety: Provided, That a person who intends to change any other matters shall report thereon. *<Amended by Act No. 11690, Mar. 23, 2013>*

(4) Drug substances registered pursuant to paragraphs (1) through (3) shall be deemed approved or notified under Article 31 (2).

(5) Except as provided for in paragraphs (1) through (3), matters necessary for registering drug substances, filing a registering for change thereto, reporting changes thereto, giving public notice of registered drug substances, and similar matters shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

Articles 31-3 and 31-4 Deleted. *<by Act No. 13219, Mar. 13, 2015>*

Article 31-5 (Renewal of Marketing Approval, etc. of Drugs)

(1) The period of validity of marketing approval or notification under Article 31 (2) and (3) shall be five years: Provided, That the period of validity thereof shall not apply to any of the following drugs: *<Amended by Act No. 11690, Mar. 23, 2013>*

1. Drug substances;
2. Drugs for export which are produced only for the purpose of export;
3. Other drugs prescribed by Ordinance of the Prime Minister, which correspond to those prescribed in subparagraphs 1 and 2.

(2) Notwithstanding paragraph (1), the period of validity of marketing approval of the drug subject to re-examination under Article 32 shall commence after the period of re-examination of the relevant drug expires.

(3) Where a person who has obtained marketing approval intends to market the relevant drug continuously after the expiration of the period of validity prescribed in paragraph (1) or (2), he/she shall obtain renewed marketing approval from, or file renewed marketing notification with, the Minister of Food and Drug Safety before the period of validity expires. *<Amended by Act No. 11690, Mar. 23, 2013>*

(4) Where any serious problem is considered to exist in the safety or effectiveness of drugs, where no data necessary for the renewal under paragraph (3) are submitted, or where other similar cases occur, the Minister of Food and Drug Safety need not renew marketing approval, or accept renewed marketing notification, of the relevant drugs. *<Amended by Act No. 11690, Mar. 23, 2013>*

(5) Where a person who has obtained marketing approval fails to manufacture a drug during the period of validity prescribed in paragraph (1), marketing approval or notification of such drug shall not be renewable in accordance with paragraph (3): Provided, That the same shall not apply to the drug that has not been manufactured due to any of unavoidable causes prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

(6) Necessary matters concerning the method of calculating the period of validity under paragraphs (1) and (2) and the standards, methods and procedures for the renewal of marketing approval or notification under paragraphs (3) and (4) shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

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

(1) Drugs falling under Article 31 (10) which are approved or notified under Article 31 (2) and (3), shall undergo a re-examination by the Minister of Food and Drug Safety, within three months after the date on which four to six years have passed depending on items from the date on which marketing approval has been granted. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013>*

(2) Necessary matters concerning methods, procedures, timing, etc. for re-examination referred to in paragraph (1) shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

Article 33 (Re-Evaluation of Drugs)

(1) The Minister of Food and Drug Safety may reevaluate drugs, etc., for which the examination of their safety and effectiveness by efficacy or by ingredient or the verification of drug equivalence are deemed necessary, among drugs approved or notified pursuant to Article 31 (2) through (4). *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

(2) Matters necessary for methods, procedures, etc. for reevaluation referred to in paragraph (1) shall be determined by the Minister of Food and Drug Safety. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 34 (Approval, etc. for Protocols of Clinical Trials, etc.)

(1) Each person who intends to conduct a clinical trial or a biological equivalence test using drugs, etc. shall prepare a protocol thereof and obtain approval from the Minister of Food and Drug Safety, and even where he/she intends to modify any approved matter, he/she shall obtain approval as prescribed by Ordinance of the Prime Minister: Provided, That where he/she intends to modify matters prescribed by Ordinance of the Prime Minister from among those in the protocol of clinical trial or the protocol of biological equivalence test, he/she shall report to the Minister of Food and Drug Safety. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

(2) Notwithstanding paragraph (1), approval under paragraph (1) may be omitted for the clinical trials and biological equivalence tests prescribed by Ordinance of the Prime Minister (hereinafter referred to as "clinical trials, etc."), such as a trial or test aimed at examining clinical effects of drugs, etc. in distribution and investigating whether any adverse event occurs under the conditions that such drugs are approved or notified. *<Amended by Act No. 11690, Mar. 23, 2013>*

(3) Any person who intends to conduct a clinical trial under paragraph (1) shall observe the following matters: *<Amended by Act No. 11690, Mar. 23, 2013>*

1. A clinical trial shall be conducted at an institute for clinical trials or an institute for biological equivalence testing designated under Article 34-2 (1): Provided, That the same shall not apply to clinical trials, etc. prescribed by Ordinance of the Prime Minister in which participation by a medical institution, other than by an institute for clinical trials or an institute for biological equivalence testing, is deemed necessary based upon the characteristics of the clinical trials, etc;

2. No person under the custody of any group care facilities prescribed by Ordinance of the Prime Minister, such as social welfare facilities, (hereafter referred to as "inmate" in this subparagraph) shall be selected as a test subject of a clinical trial, etc.: Provided, That an inmate may be selected as a test subject of a clinical trial, etc. where it is inevitable to select an inmate as a test subject of a clinical trial, etc. based upon the characteristics of the clinical trial, etc. and where selected as prescribed by Ordinance of the Prime Minister;

3. Details of a clinical trial, etc. and details of and procedures, etc. for an indemnity for any harm that may be inflicted on a test subject during the clinical trial, etc. shall be explained to the test subject of the clinical trial, etc. and consent of the test subject shall be obtained;

4. Drugs, etc. manufactured, or imported after being manufactured, in appropriate manufacturing facilities prescribed by Ordinance of the Prime Minister shall be used.

(4) No drugs, etc. manufactured or imported after being manufactured, for the purpose of clinical trials, etc. shall be used for any purpose other than for clinical trials, etc.: Provided, That where the Minister of Food and Drug Safety has granted approval, the drugs, etc. for medical treatment of any of the following persons can be used for any purpose other than for clinical trials, etc., as prescribed by Ordinance of the Prime Minister and, in such cases, paragraph (3) 3 shall apply mutatis mutandis: *<Amended by Act No. 11690, Mar. 23, 2013>*

1. A patient with a serious life-threatening disease, such as terminal cancer or AIDS;

2. An emergency patient prescribed by Ordinance of the Prime Minister, such as a patient whose life is threatened and a patient without alternative means of treatment.

(5) Where a clinical trial, etc. on pharmaceutical preparations, blood pharmaceutical preparations, gene remedial agents, cell remedial agents, etc., containing questionable composition in light of safety or effectiveness, is deemed or likely to harm the public interest or health and sanitation, the Minister of Food and Drug Safety may place limits on such clinical trial, etc. which is subject to approval under paragraph (1). *<Amended by Act No. 11690, Mar. 23, 2013>*

(6) Where any clinical trial, etc., approved under the main sentence and latter part of paragraph (1), is conducted, in violation of any approved matter, or gives rise to serious safety and ethical issues, the Minister of Food and Drug Safety may issue an order to halt the clinical trial, etc., to stop use of drugs, etc. for the clinical trial, etc., to recall or abandon such drugs, etc., or to take other necessary measures. *<Amended by Act No. 11690, Mar. 23, 2013>*

(7) Matters necessary for approval for protocols of clinical trials, etc. under paragraph (1), matters to be included in the protocols, the details of the consent of a test subject of a clinical trial, etc. and the timing and methods therefor under paragraph (3) 3, standards for a clinical trial, etc., and other necessary matters, shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 34-2 (Designation, etc. of Institutes for Clinical Trials, etc.)

(1) An institution (limited to a medical institution prescribed in Article 3 of the Medical Service Act) intending to conduct clinical trials or an institution intending to conduct biological equivalence tests shall

have necessary facilities, professional personnel and organization prescribed by Ordinance of the Prime Minister and be designated by the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 13114, Jan. 28, 2015>*

(2) Where an institution conducting clinical trials (hereinafter referred to as "institute for clinical trials") or an institution conducting biological equivalence tests (hereinafter referred to as "institute for biological equivalence testing") after obtaining designation under paragraph (1) intends to modify any designated matter, it shall obtain modified designation as prescribed by Ordinance of the Prime Minister: Provided, That where it intends to modify matters prescribed by Ordinance of the Prime Minister, it shall make a report to the Minister of Food and Drug Safety. *<Amended by Act No. 13114, Jan. 28, 2015>*

(3) Where an institute for clinical trials or institute for biological equivalence testing has conducted a clinical trial, etc., it shall comply with matters prescribed by Ordinance of the Prime Minister, such as preparing and issuing clinical trial results or biological equivalence test results and keeping records on such clinical trials, etc. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

(4) Except as otherwise expressly provided for in paragraphs (1) through (3), matters necessary for requirements for designation, procedures, methods, operation, and management of institutes for clinical trials or institutes for biological equivalence testing and other matters shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 34-3 (Designation, etc. of Non-Clinical Trial Institutes)

(1) An institute intending to conduct non-clinical trials determined and publicly notified by the Minister of Food and Drug Safety on non-human test subjects with regard to the safety and effectiveness of drugs, etc. shall have facilities, professional personnel and organization, and obtain designation from the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 13114, Jan. 28, 2015>*

(2) Where an institute which conducts non-clinical trials, designated under paragraph (1) (hereinafter referred to as "non-clinical trial institutes") intends to modify any designated matter, it shall obtain modified designation from the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister: Provided, That where he/she intends to modify matters prescribed by Ordinance of the Prime Minister, he/she shall make a report to the Minister of Food and Drug Safety. *<Amended by Act No. 13114, Jan. 28, 2015>*

(3) When a non-clinical trial institute has conducted a non-clinical trial under paragraph (1), it shall comply with the matters prescribed by Ordinance of the Prime Minister, such as preparing and issuing non-clinical trial results and keeping records on such non-clinical trial, etc. *<Amended by Act No. 11690, Mar. 23, 2013>*

(4) Except as otherwise expressly provided for in paragraphs (1) through (3), matters necessary for the designation requirements, procedures, methods, operation, and management of non-clinical trial institutes and other matters shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 34-4 (Education of Persons Conducting Clinical Trials, etc.)

(1) The head of an institute for clinical trials, head of an institute for biological equivalence testing (hereinafter referred to as "institution conducting clinical trials, etc.") and a person intending to conduct clinical trials, etc. pursuant to Article 34 (1) shall employ the following personnel (hereinafter referred to as "persons conducting clinical trials, etc.") receive education to enhance professionalism and protect persons subject to clinical trials (hereinafter referred to as "education on clinical trials, etc."):

1. Persons responsible for conducting clinical trials, etc. in an institution conducting clinical trials, etc.;
2. Persons monitoring the supervision, verification, and examination of clinical trials, etc.;
3. Persons in charge of conducting clinical trials, etc. under the entrustment and supervision of the persons responsible under subparagraph 1 in an institution conducting clinical trials, etc.;
4. Persons engaged in protecting rights and safety of persons subject to clinical trials, etc., who participate in clinical trials., etc. which are prescribed by Ordinance of the Prime Minister.

(2) The Minister of Food and Drug Safety may order the heads of institutions conducting clinical trials, etc. and persons intending to conduct clinical trials, etc. to have persons engaged in clinical trials, etc., who are employed thereby, receive education on clinical trials, etc.

(3) The Minister of Food and Drug Safety may designate specialized organizations, institutions, etc. related to clinical trials, etc. as an institution to provide education on clinical trials, etc. (hereinafter referred to as "clinical trial education providers, etc."). In such cases, the Minister of Food and Drug Safety shall publicly notify the details of designation.

(4) Institutions providing education on clinical trials, etc. shall observe matters prescribed by Ordinance of the Prime Minister, such as putting education on clinical trials, etc. on record, keeping the record, etc.

(5) In addition to matters prescribed in paragraphs (1) and (4), matters necessary for education on clinical trials, etc., such as details, hours, and methods of education, education fees, etc., matters necessary for requirements and procedures for designation of clinical trial education providers, etc., operation thereof, revocation of designation, etc. shall be prescribed by Ordinance of the Prime Minister.

Article 35 (Conditional Permission)

(1) In granting permission under Article 31 (1) and (2), the Minister of Food and Drug Safety may grant permission for the business of manufacturing drugs or items prescribed by Ordinance of the Prime Minister, on condition that the facilities referred to in Article 31 (1) be installed within a fixed period. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

(2) If a person who has obtained permission under paragraph (1) fails to be equipped with proper facilities without justifiable grounds within the period under paragraph (1), the Minister of Food and Drug Safety shall revoke such permission. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 35-2 (Preliminary Examination of Marketing Approval of Drugs, etc.)

(1) A person who intends to obtain marketing approval, or file marketing notification, of drugs, etc. pursuant to Article 31 and a person who intends to conduct a clinical trial, etc. pursuant to Article 34 may

request, in advance, the Minister of Food and Drug Safety to examine standards for preparing documents necessary for marketing approval, notification, approval, etc. *<Amended by Act No. 11690, Mar. 23, 2013>*

(2) Upon receipt of a request under paragraph (1), the Minister of Food and Drug Safety shall confirm such request and inform the applicant of examination results in writing. *<Amended by Act No. 11690, Mar. 23, 2013>*

(3) In cases of marketing approval, notification, approval, etc. referred to in Articles 31 and 34, the Minister of Food and Drug Safety shall take into consideration the examination results referred to in paragraph (2). *<Amended by Act No. 11690, Mar. 23, 2013>*

(4) Matters necessary for preliminary examination under paragraph (1), such as the subject matter, scope, procedures and methods shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 36 (Supervisors of Drug Manufacturing, etc.)

(1) A manufacturer of drugs, etc. (excluding a quasi-drug manufacturer manufacturing only items falling under subparagraph 7 (a) of Article 2) shall assign the necessary number of pharmacists or oriental medicine pharmacists to each of his/her production facilities and have them manage manufacturing, as prescribed by Ordinance of the Prime Minister: Provided, That in cases of an industry manufacturing biological preparations, cellular therapy products or gene therapy products, the manufacturer may have a physician approved by the Minister of Food and Drug Safety or a professional with bacteriological knowledge prescribed by Ordinance of the Prime Minister manage manufacturing. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

(2) A quasi-drug manufacturer manufacturing only items falling under subparagraph 7 (a) of Article 2 shall assign technicians approved by the Minister of Food and Drug Safety to each of his/her production facilities and entrust them with supervision over manufacturing affairs: Provided, That where the manufacturer himself/herself is a technician approved by the Minister of Food and Drug Safety, and supervises manufacturing affairs at his/her production facility, he/she need not assign an additional technician to such production facility. *<Amended by Act No. 11690, Mar. 23, 2013>*

(3) Where a manufacturer of drugs, etc. intends to assign a person to supervise manufacturing affairs of drugs, etc. (hereinafter referred to as "manufacturing supervisor") pursuant to paragraph (1) or (2), he/she shall report to the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. *<Newly Inserted by Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>*

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

(1) A manufacturing supervisor shall comply with the matters prescribed by Ordinance of the Prime Minister 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; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>*

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

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

Article 37-2 (Education for Manufacturing Supervisors, etc.)

(1) Each manufacturing supervisor shall receive education on ensuring safety and efficiency, manufacturing, and quality control of drugs, etc., regularly.

(2) If necessary to prevent harm to public health, the Minister of Food and Drug Safety may order manufacturing supervisors to receive education referred to in paragraph (1). *<Amended by Act No. 11690, Mar. 23, 2013>*

(3) Each manufacturing supervisor (including a replaced manufacturing supervisor where such replacement was reported pursuant to subparagraph 3 of Article 40) shall receive education referred to in paragraph (1) within six months from the date when he/she begins his/her work as a manufacturing supervisor: Provided, That the same shall not apply where he/she received the same education within two years before becoming a manufacturing supervisor. *<Amended by Act No. 13655, Dec. 29, 2015>*

(4) For the purposes of providing education referred to in paragraphs (1) through (3), the Minister of Food and Drug Safety may designate and publicly notify a relevant professional organization or institution as an education institution. *<Amended by Act No. 11690, Mar. 23, 2013>*

(5) Each education institution designated under paragraph (4) (hereinafter referred to as "education institution for manufacturing supervisors"), shall observe matters prescribed by Ordinance of the Prime Minister, such as issuing certificates of completion of education, keeping and retaining education records, etc. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

(6) Except as otherwise provided for in paragraphs (1) through (5), matters necessary for educating manufacturing supervisors, such as details, hours, and methods of education, education fees, etc., and matters necessary for requirements and procedures for designating an education institution, operation thereof, revocation of such designation, etc. shall be prescribed by Ordinance of the Prime Minister. *<Newly Inserted by Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

Article 37-2 (Education for Manufacturing Supervisors, etc.)

(1) Each manufacturing supervisor shall receive education on ensuring safety and efficiency, manufacturing, and quality control of drugs, etc. regularly.

(2) If necessary to prevent harm to public health, the Minister of Food and Drug Safety may order manufacturing supervisors to receive education referred to in paragraph (1). *<Amended by Act No. 11690, Mar. 23, 2013>*

(3) Each manufacturing supervisor (including a replaced manufacturing supervisor where such replacement was reported pursuant to Article 40 (1) 3) shall receive education referred to in paragraph (1)

within six months from the date when he/she begins his/her work as a manufacturing supervisor: Provided, That the same shall not apply where he/she received the same education within two years before becoming a manufacturing supervisor. *<Amended by Act No. 13655, Dec. 29, 2015; Act No. 14328, Dec. 2, 2016>*

(4) For the purposes of providing education referred to in paragraphs (1) through (3), the Minister of Food and Drug Safety may designate and publicly notify a relevant professional organization or institution as an education institution. *<Amended by Act No. 11690, Mar. 23, 2013>*

(5) Each education institution designated under paragraph (4) (hereinafter referred to as "education institution for manufacturing supervisors"), shall observe matters prescribed by Ordinance of the Prime Minister, such as issuing certificates of completion of education, keeping and retaining education records, etc. *<Newly Inserted by Act No. 13114, Jan. 28, 2015>*

(6) Except as otherwise provided for in paragraphs (1) through (5), matters necessary for educating manufacturing supervisors, such as details, hours, and methods of education, education fees, etc., and matters necessary for requirements and procedures for designating an education institution, operation thereof, revocation of such designation, etc. shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

Article 37-3 (Post-Marketing Safety Control of Drugs)

(1) A person who has obtained marketing approval of drugs shall employ a physician, pharmacist, or oriental medicine pharmacist to perform the duties of post-marketing safety control, such as re-examining new drugs, etc., re-evaluating drugs, and reporting side effects, as prescribed by Ordinance of the Prime Minister: Provided, That a person who has obtained marketing approval of a drug to be used for animals only may perform the duties of post-marketing safety control after employing a veterinarian. *<Amended by Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

(2) A person who performs affairs of safety control under paragraph (1) (hereinafter referred to as a "safety control manager"), shall comply with the matters prescribed by Ordinance of the Prime Minister, regarding the safety control of drugs in distribution. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 37-4 (Education of Safety Control Managers)

(1) Each safety control manager shall receive education on the duties of safety control under Article 37-3 (1) regularly.

(2) If necessary to prevent harm to public health, the Minister of Food and Drug Safety may order safety control managers to receive occasional education in addition to receiving regular education pursuant to paragraph (1).

(3) Each safety control manager (including a replaced safety manager where such placement is reported under subparagraph 3 of Article 40) shall receive education prescribed in paragraph (1) within six months from the date he/she begins his/her work as a safety control manager: Provided, That this shall not apply where he/she received the same education within two years before becoming a safety control manager. *<Amended by Act No. 13655, Dec. 29, 2015>*

(4) The Minister of Food and Drug Safety may designate a relevant professional organization or institution as an education institution to provide education prescribed in paragraphs (1) through (3).

(5) Each education institution prescribed in paragraphs (4), shall issue certificates of completion of education to persons who complete education courses, and keep and retain education records, as prescribed by Ordinance of the Prime Minister.

(6) Except as otherwise provided for in paragraphs (1) through (4), matters necessary for education, such as details, hours, and methods of education, education fees, etc. and matters necessary for the designation, operation, revocation of designation of an education institution, etc. shall be prescribed by Ordinance of the Prime Minister.

Article 37-4 (Education of Safety Control Managers)

(1) Each safety control manager shall receive education on the duties of safety control under Article 37-3 (1), regularly.

(2) If necessary to prevent harm to public health, the Minister of Food and Drug Safety may order safety control managers to receive occasional education in addition to receiving regular education pursuant to paragraph (1).

(3) Each safety control manager (including a replaced safety manager where such placement is reported under Article 40 (1) 3) shall receive education prescribed in paragraph (1) within six months from the date he/she begins his/her work as a safety control manager: Provided, That this shall not apply where he/she received the same education within two years before becoming a safety control manager. *<Amended by Act No. 13655, Dec. 29, 2015; Act No. 14328, Dec. 2, 2016>*

(4) The Minister of Food and Drug Safety may designate a relevant professional organization or institution as an education institution to provide education prescribed in paragraphs (1) through (3).

(5) Each education institution prescribed in paragraphs (4), shall issue certificates of completion of education to persons who complete education courses, and keep and retain education records, as prescribed by Ordinance of the Prime Minister.

(6) Except as otherwise provided for in paragraphs (1) through (4), matters necessary for education, such as details, hours, and methods of education, education fees, etc. and matters necessary for the designation, operation, revocation of designation of an education institution, etc. shall be prescribed by Ordinance of the Prime Minister.

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

(1) A manufacturer of drugs, etc. or a person who has obtained marketing approval of drugs shall comply with the matters prescribed by Ordinance of the Prime Minister with respect to the manufacture and quality control (including self-test) of drugs, etc. and other production control thereof. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>*

(2) A person who has obtained marketing approval of drugs or a quasi-drug manufacturer shall report the production performance, etc. of drugs, etc. to the Minister of Food and Drug Safety or the president of the Korea Pharmaceutical Information Service under Article 47-3 (1), as prescribed by Ordinance of the Prime

Minister. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013; Act No. 14328, Dec. 2, 2016>*

Article 38-2 (Drug Identification Mark)

(1) A person who has obtained marketing approval of a drug in dosage form determined and publicly notified by the Minister of Food and Drug Safety shall place a mark on a drug distinguishable from other drugs (hereinafter referred to as "identification mark"), and have the identification mark registered with the Minister of Food and Drug Safety and release the drug in the market.

(2) Where a person who had registered an identification mark pursuant to paragraph (1) changes the identification mark, he/she shall register the change with the Minister of Food and Drug Safety.

(3) The Minister of Food and Drug Safety may entrust a juristic person established pursuant to Article 67 or a relevant specialized institution prescribed by Presidential Decree with the duties of registering identification marks under paragraphs (1) and (2).

(4) Matters necessary for the operation of identification mark system, such as the methods of identification marking, procedures for registration, etc. under paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

Article 39 (Recall of Hazardous Drugs, etc.)

(1) Where any of the following persons becomes aware that a drug, etc. has any issues as to safety and efficacy, in violation of Article 53 (1), 61 (including where such provision applies mutatis mutandis in Article 66), or 62 (including where such provision applies mutatis mutandis in Article 66), he/she shall promptly recall the drugs, etc. in circulation or take necessary measures for recall. In such cases, a person falling under any of subparagraphs 1 through 3 shall pre-report a recall plan to the Minister of Food and Drug Safety: *<Amended by Act No. 13114, Jan. 28, 2015>*

1. A person who has obtained marketing approval of drugs;
2. A quasi-drug manufacturer;
3. An importer of drugs, etc. prescribed in Article 42 (2);
4. A distributor of drugs, etc.;
5. A pharmacy founder;
6. A medical institution founder;
7. A person prescribed by Ordinance of the Prime Minister, among persons eligible to sell or handle drugs pursuant to this Act or other Acts.

(2) The Minister of Food and Drug Safety, Mayors/Do Governors or heads of Sis/Guns/Gus may release or lift the administrative dispositions issued pursuant to Article 76 to persons who have obtained marketing approval of drugs, manufacturers of quasi-drugs or importers of drugs, etc., pharmacy founders and drug distributors, who conscientiously perform the recall or measures necessary for the recall in accordance with paragraph (1), as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

(3) Matters necessary for the ranking of harms and standards for appraisal thereof necessary for the recall of drugs, etc., recall plans, procedures for recall and abandonment and follow-up measures for recalled drugs, etc. in accordance with paragraph (1) shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>*

Article 40 (Reports on Discontinuance, etc. of Business)

Where a manufacturer of drugs, etc., or a person who has obtained marketing approval, falls under any of the following cases, he/she shall report such fact to the Minister of Food and Drug Safety within 20 days: Provided, That the same shall not apply where the period of suspension of business is under one month: *<Amended by Act No. 11690, Mar. 23, 2013>*

1. Where a factory or a contract manufacturing business office is closed down or its operation is temporarily suspended;
2. Where a factory or a contract manufacturing business office, the operation of which is temporarily suspended, resumes its operation;
3. Where a manufacturing supervisor, a safety control manager, and other matters prescribed by Ordinance of the Prime Minister have been changed.

Article 40 (Reports on Discontinuance, etc. of Business)

(1) Where a manufacturer of drugs, etc., or a person who has obtained marketing approval, falls under any of the following cases, he/she shall report such fact to the Minister of Food and Drug Safety within seven days: Provided, That the same shall not apply where the period of suspension of business is under one month: *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 14328, Dec. 2, 2016>*

1. Where a factory or a contract manufacturing business office is closed down or its operation is temporarily suspended;
2. Where a factory or a contract manufacturing business office, the operation of which is temporarily suspended, resumes its operation;
3. Where a manufacturing supervisor, a safety control manager, and other matters prescribed by Ordinance of the Prime Minister have been changed.

(2) Where a manufacturer of drugs, etc., or a person who has obtained marketing approval intends to report a discontinuance or a temporary suspension of business under paragraph (1), he/she shall recall the drugs, etc. in circulation or take necessary measures for recall under Article 39 or take other necessary measures, as prescribed by Ordinance of the Prime Minister. *<Newly Inserted by Act No. 14328, Dec. 2, 2016>*

(3) Where a manufacturer of drugs, etc., or a person who has obtained marketing approval files a report of resuming business under paragraph (1) 2, he/she shall attach and submit the documents or data prescribed by Ordinance of the Prime Minister, such as the result of inspecting facilities of drugs, etc. factories, the status of drugs, etc. possession, to the Minister of Food and Drug Safety: Provided, That where a manufacturer of drugs, etc., or a person who has obtained marketing approval, whose period of suspension of business is less than one year, files a report of resuming business, the Minister of Food and Drug Safety

may exempt the duty to submit documents or data. *<Newly Inserted by Act No. 14328, Dec. 2, 2016>*

Article 41 (Manufacturing Pharmacy Medication)

(1) When pharmacy founders intend to manufacture pharmacy medications or dispensaries of medical institutions designated by the Minister of Health and Welfare intend to manufacture medications, they shall report the relevant items to the head of a Si/Gun/Gu, as prescribed by Ordinance of the Prime Minister, following consultation with the Minister of Health and Welfare: Provided, That where a dispensary of a medical institution, the incorporation of which is permitted by a Mayor/Do Governor pursuant to the Medical Service Act, intends to manufacture medications, it shall report to the relevant Mayor/Do Governor. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

(2) The scope of pharmacy medications and dispensary medications, facilities of dispensaries, and other necessary matters shall be prescribed by Ordinance of the Prime Minister, following consultation with the Minister of Health and Welfare. *<Amended by Act No. 852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

Article 42 (Permission, etc. for Importation of Drugs, etc.)

(1) Each person, who intends to engage in the business of importing drugs, etc., shall file a report on importation business with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister, and obtain marketing approval from, or file marketing notification with, the Minister of Food and Drug Safety for each product, as prescribed by Ordinance of the Prime Minister. The same shall also apply where he/she intends to modify the matters approved or notified. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

(2) Notwithstanding paragraph (1), the Minister of National Defense or a person who has filed a report on importation business pursuant to the former part of paragraph (1) (hereinafter referred to as "importer") may import drugs, etc. without obtaining marketing approval, or filing marketing notification, of each product under paragraph (1) in any of following cases: *<Amended by Act No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

1. Where the Minister of National Defense intends to import drugs, etc, not produced domestically for any urgent military purpose, following consultation with the Minister of Food and Drug Safety on the items and quantity of the drugs, etc.;
2. Where an importer intends to import drug substances to manufacture drugs, etc., or the drugs, etc. prescribed by Ordinance of the Prime Minister, including drugs, etc. for clinical trials.

(3) Each importer shall have necessary facilities, such as business offices, compliant with standards for installation prescribed by Presidential Decree. *<Amended by Act No. 13114, Jan. 28, 2015>*

(4) None of the following persons shall file a report on importation business under paragraph (1). In cases of corporations, the same shall apply where the representative of a corporation falls under any of the following cases: *<Newly Inserted by Act No. 13114, Jan. 28, 2015>*

1. A person falling under any of the subparagraphs of Article 5;

2. A person for whom one year has not passed since a business office is closed pursuant to Article 76;

3. A person not yet reinstated after having been declared bankrupt.

(5) Articles 31 (7), (10) and (11), 31-2, 31-5, 32, 33, 35-2, 36, 37, 37-2 through 37-4, 38, 38-2, 40, 50-2 through 50-10, 69-3 and 75 shall apply mutatis mutandis to the drugs, etc. imported pursuant to paragraph (1) or the importers thereof. In such cases, "manufacture" or "production" shall be construed as "import", "manufacturers or persons who have obtained marketing approval" as "importers", respectively, and "factory or contract manufacturing business office" as "business office", respectively. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10512, Mar. 30, 2011; Act No. 10788, Jun. 7, 2011; Act No. 11118, Dec. 2, 2011; ; Act No. 11421, May 14, 2012; Act No. 12450, Mar. 18, 2014; Act No. 13114, Jan. 28, 2015; Act No. 13219, Mar. 13, 2015>*

(6) Matters necessary for filing reports on importation business, products subject to marketing approval or notification, standards, conditions, management, etc. under paragraph (1) shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10512, Mar. 30, 2011; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

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

(1) Any person who intends 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 permission from the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

(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 using the horns of rhinoceros or the 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.

Article 44 (Distribution of Drugs)

(1) No person, other than pharmacy founders (including pharmacists or herb-pharmacists working for a pharmacy; hereafter the same shall apply in Articles 47, 48 and 50), shall sell or obtain drugs for sale: Provided, That the same shall not apply where a person who has obtained marketing approval of drugs, or an importer, sells drugs manufactured or imported to a person eligible to manufacture or sell drugs according to this Act. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 13655, Dec. 29, 2015>*

(2) Notwithstanding paragraph (1), any of the following persons may sell or obtain drugs for sale: *<Amended by Act No. 11421, May 14, 2012; Act No. 14328, Dec. 2, 2016>*

1. The Korea Orphan and Essential Drug Center established pursuant to Article 91;

1-2. A seller of safe and readily available drugs who has been registered under Article 44-2 (applicable only to the cases where safe and readily available drugs referred to in Article 44-2 (1) are sold);

2. A herb druggist or drug wholesaler who has obtained a license pursuant to Article 45.

Article 44-2 (Registration of Sellers of Safe and Readily Available Drugs)

(1) A person who intends to sell safe and readily available drugs (referring to drugs which, among over-the-counter drugs, are emergently used mainly for minor symptoms at the sole discretion of patients and are prescribed and publicly notified by the Minister of Health and Welfare within the limit of 20 items taking into consideration the components, side effects, content, dosage form, awareness, purchase availability, etc. of the relevant items; hereinafter the same shall apply) at a place which is not a pharmacy shall file for registration for a seller of safe and readily available drugs with the head of the competent Si/Gun/Gu.

(2) A person who intends to file for registration for a seller of safe and readily available drugs under paragraph (1) shall have a year-round shop that opens 24 hours a day, and shall meet the criteria for registration prescribed by Ordinance of the Ministry of Health and Welfare in consideration of the convenience in use by local residents, the availability of recall of hazardous drugs, etc.

(3) If a seller of safe and readily available drugs intends to alter any matter prescribed by Ordinance of the Ministry of Health and Welfare among the matters registered, he/she shall file for registration to change registration details with the head of the competent Si/Gun/Gu.

(4) Where a seller of safe and readily available drugs discontinues the sale of safe and readily available drugs, or suspends such business or resumes the suspended business, he/she shall file a report thereon with the head of the competent Si/Gun/Gu: Provided, That the same shall not apply if the period of suspension is less than one month.

(5) Matters necessary for filing for registration, filing for registration to change registration details pursuant to paragraphs (1) through (3) and for the methods, procedures, etc. for reporting on the discontinuation, suspension, resumption of the sale, etc. under paragraph (4) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 44-3 (Education for Sellers of Safe and Readily Available Drugs)

(1) A person who intends to file for registration for a seller of safe and readily available drugs under Article 44-2 (1) shall receive education in advance on safety assurance and quality control of safe and readily available drugs.

(2) If deemed necessary to prevent harm to public health, the Minister of Health and Welfare may order a seller of safe and readily available drugs (including his/her employees) to receive education on the safety assurance and quality control of safe and readily available drugs.

(3) In order to provide education referred to in paragraphs (1) and (2), the Minister of Health and Welfare may designate a relevant organization or institution as an education institution.

(4) Matters necessary for the curricula, time, method, procedures, fees, etc. of education under paragraph (1) and (2) and matters necessary for the designation, operation, revocation of designation, etc. of an education institution under paragraph (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 44-4 (Matters to be Observed by Sellers of Safe and Readily Available Drugs)

Each seller of safe and readily available drugs shall observe the following matters:

1. He/she shall manage his/her facilities and safe and readily available drugs in a manner that does not impede health and sanitation and the efficacy of drugs;
2. He/she shall thoroughly oversee his/her employees in order to prevent any sanitary incident;
3. He/she shall observe the matters prescribed by Ordinance of the Ministry of Health and Welfare, such as the limit of quantity to sell at one time, age restricted sales, etc;
4. He/she shall observe other matters corresponding to subparagraphs 1 through 3 and prescribed by Ordinance of the Ministry of Health and Welfare.

Article 44-5 (Application Mutatis Mutandis)

(1) Articles 39 (1), 47 (1), 50 (1) and (3), 56 (2), 68-7, 69, 71, 71 (2) shall apply mutatis mutandis to sellers of safe and readily available drugs registered under Article 44-2 (1). In such cases, "pharmacy founder" shall be construed as "seller of safe and readily available drugs registered under Article 44-2 (1)", and "over-the-counter drugs" referred to in Article 50 (3) as "safe and readily available drugs under Article 44-2 (1)."

(2) Article 47-3 (2) shall apply mutatis mutandis to sellers of safe and readily available drugs registered under Article 44-2 (1). In such cases, "pharmacy" shall be construed as "seller of safe and readily available drugs." *<Amended by Act No. 14328, Dec. 2, 2016>*

Article 45 (Licenses of Drug Distribution Business)

(1) Each 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 any licensed matter. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011>*

(2) Each person, who intends to obtain a license pursuant to paragraph (1), shall have facilities as classified hereunder: *<Amended by Act No. 10512, Mar. 30, 2011; Act No. 12450, Mar. 18, 2014; Act No. 13114, Jan. 28, 2015>*

1. In cases of a herb druggist, a business office and other facilities meeting the standards for facilities prescribed by Presidential Decree;
2. In cases of a drug wholesaler, a business office, a warehouse, and other facilities meeting the standards for facilities prescribed by Presidential Decree. In such cases, the scale of the warehouse shall be at least 165 square meters: Provided, That where he/she handles only imported drugs, reagents, or drug substances, the scale of his/her warehouse shall be at least 66 square meters; where he/she handles only animal drugs, the scale of his/her warehouse shall be at least 33 square meters; where he/she

handles only herb drugs, high pressure gas for medical purposes, and radiopharmaceuticals, standards for the scale of warehouses shall not be applied.

(3) A license for a herb druggist under paragraph (1) shall be granted to a person who has passed the examination for herb druggists 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 licensed under paragraph (1) may sell herb drugs after mixing them in accordance with a prescription recorded in an established herb book or with a prescription of a oriental medical doctor.

(5) A drug wholesaler licensed under paragraph (1) shall employ a pharmacist to manage the wholesale business, and a herb wholesaler shall employ any of the following persons to manage the herb wholesale business: Provided, That where the drug wholesaler who, himself/herself, is a pharmacist manages his/her business in person, or any of the following herb wholesalers manages his/her business in person, this shall not apply: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

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

(6) Where a drug wholesaler or herb wholesaler intends to employ a person in charge of the business pursuant to paragraph (5), he/she shall file a report with the head of a Si/Gun/Gu, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Newly Inserted by Act No. 10788, Jun. 7, 2011>*

(7) Matters necessary for the standards, conditions, and management of licenses 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>*

(8) Notwithstanding paragraph (5), in cases of outsourcing distribution and management, such as storage and delivery of drugs, to any other drug wholesaler who meets the requirements prescribed by Ordinance of the Ministry of Health and Welfare, a drug wholesaler need not employ a person who manages the business pursuant to paragraph (5): Provided, That in such cases, a person to whom distribution and management affairs are outsourced shall employ a person in charge of the business pursuant to paragraph (5), as prescribed by Ordinance of the Ministry of Health and Welfare. *<Newly Inserted by Act No. 13655, Dec. 29, 2015>*

Article 46 (Grounds for Disqualification of Licenses of Herb Druggists or Drug Wholesalers)

None of the following persons shall be licensed as a herb druggist or drug wholesaler: *<Amended by Act No. 10788, Jun. 7, 2011>*

1. A person falling under any of subparagraphs 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 medical institution founder (where the medical institution is a juristic person, the officers and staff thereof) or a pharmacy founder;

4. A person who was declared bankrupt but has not yet been reinstated.

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

(1) Each of the following persons shall comply with the following matters to establish a distribution system of drugs, etc. and to maintain order in distribution: *<Amended by Act No. 13655, Dec. 29, 2015>*

1. A person who has obtained marketing approval of drugs, an importer, or a drug wholesaler (hereinafter referred to as “drug provider”) shall not engage in the following activities:

(a) Retailing Drugs;

(b) Selling drugs to persons other than pharmacy founders; sellers of safe and readily available drugs; herb druggists; druggists or drug sellers referred to in Article 5 of the Addenda of partially amended Pharmaceutical Affairs Act No. 8365 (hereinafter referred to as “founder of pharmacy, etc."); other drug wholesalers; and other persons entitled to sell drugs pursuant to this Act;

2. Notwithstanding subparagraph 1, a drug provider may retail or sell drugs for public interests or for other purposes prescribed by Presidential Decree;

3. A drug wholesaler or founder of pharmacy, etc. shall comply with the following matters:

(a) A drug wholesaler or founder of pharmacy, etc. shall not purchase drugs from a person other than a drug provider: Provided, That this shall not apply where he/she purchases drugs from the founder of pharmacy, etc. who ceased his/her business or where a founder of pharmacy, etc. purchases drugs from other founders of pharmacy, etc. urgently since no drug prescribed by a physician or dentist exists in his/her pharmacy;

(b) A drug wholesaler shall store drugs in the warehouses meeting the requirements of Article 45 (2);

4. A drug wholesaler, founder of pharmacy, etc., and other persons entitled to sell drugs pursuant to this Act shall comply with the following matters:

(a) Matters regarding distribution management on safety and quality of drugs, etc. prescribed by Ordinance of the Prime Minister, such as prohibition of the distribution of unsanitary or harmful drugs, and compliance by drug wholesalers with the standards for qualify control of drugs in distribution;

(b) Matters regarding distribution management and maintenance of order in sales of drugs prescribed by Ordinance of the Ministry of Health and Welfare, such as prohibition of disturbing market order, including cornering of market; prohibition of enticing consumers by name, etc. of pharmacy; or prohibition of dispensing or selling drugs in excess of the limits.

(2) No drug provider (including the representative, directors or other workers of a corporation or workers of a non-corporation; hereafter the same shall apply in this Article) shall offer any money, articles, convenience, labor, entertainment or other economic benefits (hereinafter referred to as "economic benefits, etc.") to pharmacists, oriental medicine pharmacists (including persons working for the relevant pharmacy; hereafter the same shall apply in this Article), medical personnel, medical institution founders

(including the representative, directors, and other workers of a corporation; hereafter the same shall apply in this Article) or persons working for a medical institution for the purpose of sales promotion, such as adoption of drugs, inducement of prescription and maintenance of transaction, nor assist pharmacists, oriental medicine pharmacists, medical personnel, medical institution founders or persons working for a medical institution to provide economic benefits, etc. to the relevant pharmacy or medical institution: Provided, That the same shall not apply to the economic benefits, etc. to the extent prescribed by Ordinance of the Ministry of Health and Wealth, following consultation with the Minister of Food and Drug Safety, such as provision of samples, support for symposiums, support for clinical trials, product presentation, discount under the price terms, and post-marketing survey (hereinafter referred to as "provision of samples, etc."). *<Newly Inserted by Act No. 10324, May 27, 2010; Act No. 11690, Mar. 23, 2013; Act No. 13655, Dec. 29, 2015>*

(3) No pharmacist or oriental medicine pharmacist shall receive any economic benefits, etc. provided by a drug provider for sales promotion, such as adoption of drugs, inducement of prescription and maintenance of transaction, nor assist the relevant pharmacy, etc. to acquire such economic benefits, etc.: Provided That the same shall not apply to the economic benefits, etc. to the extent prescribed by Ordinance of the Ministry of Health and Welfare following consultation with the Minister of Food and Drug Safety, such as provision of samples, etc. *<Newly Inserted by Act No. 10324, May 27, 2010; Act No. 11690, Mar. 23, 2013; Act No. 13655, Dec. 29, 2015>*

(4) No drug wholesaler shall sell drugs, directly or through another drug wholesaler, to the medical institution or pharmacy with which he/she has any of the following special relations: Provided, That the same shall not apply to herb drugs: *<Newly Inserted by Act No. 10788, Jun. 7, 2011>*

1. Where a person who has any of the following special relations with a drug wholesaler (hereinafter referred to as "related party") is a medical institution founder or a pharmacy founder, the relevant medical institution or pharmacy:

(a) If a drug wholesaler is an individual, his/her relatives within the second degree of consanguinity or affinity (referring to relatives defined in Article 767 of the Civil Act; hereinafter the same shall apply);

(b) If a drug wholesaler is a juristic person, an executive officer of the relevant juristic person, and his/her relatives within the second degree of consanguinity or affinity;

(c) If a drug wholesaler is a juristic person, a person who actually controls the relevant juristic person (referring to a person who has contributed or owns the share exceeding 50/100 of the total amount of contributions, the total issued stocks, or the total contributed shares of the relevant juristic person, and a person who exercises a dominant influence over an organization of executive officers or business operation, etc.; hereinafter the same shall apply);

(d) If a related party referred to in item (c) is a juristic person, an executive officer of the relevant juristic person or a person who actually controls the relevant juristic person;

(e) If a related party referred to in items (c) and (d) is an individual, his/her relatives within the second degree of consanguinity or affinity;

(f) A juristic person which actually controls drug wholesalers;

(g) A juristic person actually controlled by a related party under this subparagraph;

(h) An employee of a drug wholesaler or of a related party under this subparagraph (referring to an executive officer in cases of a juristic person, and commercial employees and employees by an employment contract in cases of individuals; hereafter the same shall apply in this Article);

2. Where a person who has any of the following relations with a medical institution founder or a pharmacy founder is a drug wholesaler, the relevant medical institution or pharmacy:

(a) If a medical institution founder or a pharmacy founder is an individual, his/her relatives within the second degree of consanguinity or affinity;

(b) If a medical institution founder is a juristic person, an executive officer of the relevant juristic person, and their relatives within the second degree of consanguinity or affinity;

(c) If a medical institution founder is a juristic person, a person who actually controls the relevant juristic person;

(d) If a related party under item (c) is a juristic person, an executive officer of the relevant juristic person, and a person who actually controls the relevant juristic person;

(e) If a related party under items (c) and (d) is an individual, his/her relatives within the second degree of consanguinity or affinity;

(f) A juristic person which actually controls a corporate medical institution;

(g) A juristic person actually controlled by a related party under this subparagraph;

(h) Employees of a medical institution founder, a pharmacy founder, or a related party under this subparagraph.

Article 47-2 (Submission, etc. of Expense Report on Details of Providing Economic Interests, etc.)

(1) A drug provider shall prepare an expense report on economic interests, etc. which he/she provided to pharmacists, oriental medicine pharmacists, medical personnel, medical institution founders, or persons working for a medical institution, within three months after the termination of each fiscal year, as prescribed by Ordinance of the Ministry of Health and Wealth, and shall retain the relevant expense report, books related thereto, and base data for five years.

(2) Where deemed necessary, the Minister of Health and Wealth may request the submission of the expense report, books related thereto, and base data under paragraph (1). In such cases, a drug provider shall comply therewith without justifiable grounds.

Article 47-3 (Designation and Operation of Korea Pharmaceutical Information Service)

(1) The Minister of Health and Welfare may designate a specialized institution or organization as an institution for information control of distribution of drugs (hereinafter referred to as the "Korea Pharmaceutical Information Service"), as prescribed by Presidential Decree, for collection, investigation, processing, utilization and provision of information on distribution of drugs, such as manufacture,

importation, supply and details of use of drugs and require it to perform such affairs. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) Where a person who has obtained marketing approval of drugs, an importer, or a drug wholesaler has supplied medical institutions, pharmacies, and drug wholesalers with drugs, he/she shall submit details of such supply to the Korea Pharmaceutical Information Service, as prescribed by Ordinance of the Ministry of Health and Welfare: Provided, That the submission of details of supply may be omitted when he/she has supplied drugs in a manner that details of supply can be verified, as prescribed by Ordinance of the Ministry of Health and Welfare.

(3) The Korea Pharmaceutical Information Service may request the State, local governments, and other public organizations, etc. to provide necessary data for efficient control of information on distribution of drugs, and the State, local governments, and other public organizations, etc. upon receipt of requests shall comply with such requests, except in extenuating circumstances. In such cases, such data provided to the Korea Pharmaceutical Information Service shall be utilized free of royalties, fees, etc.

(4) The Minister of Health and Welfare and the Minister of Food and Drug Safety may order the president of the Korea Pharmaceutical Information Service to report the current status of management and distribution of drugs. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

(5) The Minister of Health and Welfare may fully or partially subsidize expenses incurred in operation of the Korea Pharmaceutical information Service. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(6) Matters necessary for operation, etc. of the Korea Pharmaceutical Information Service shall be prescribed by Presidential Decree.

Article 48 (Prohibition of Sale of Unsealed Drugs)

No person shall remove the seal on a container or package of drugs affixed by a manufacturer of the drugs, etc., a person who has obtained marketing approval of the drugs, etc., or an importer pursuant to Article 63 for the purpose of sales of such drugs: Provided, That 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 physician, dentist, or oriental medical doctor, or pursuant to the provisos to Article 23 (3) and (6) or to Article 4 of the Addenda of the amended Pharmaceutical Affairs Act (Act No. 4731);
2. Where a pharmacy founder sells prepared herb drugs 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: Provided, That the same shall not apply where approval therefor is obtained from the head of a Si/Gun/Gu.

(2) No pharmacy founder shall sell any prescription drugs without prescriptions issued by a physician or dentist: Provided, That the same shall not apply where prescription 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) A pharmacy founder may sell over-the-counter drugs without prescriptions issued by a physician or a dentist.

(4) Where a pharmacy founder deems it necessary to sell over-the-counter drugs, he/she may provide medication counselling.

Article 50-2 (Registration of Drug Patent)

(1) Each person, who has obtained marketing approval of a drug referred to in Article 31 (2) and (3) or revised approval of a drug referred to in paragraph (9) of the same Article (hereinafter referred to as “marketing approval or revised approval”), shall file an application for registration of the patent information of the drug in the drug patent list (hereinafter referred to as “patent list”) in which the Minister of Food and Drug Safety registers and manages patents of drugs approved (hereinafter referred to as “drug patent”).

(2) Each person, who intends to file an application for registration of the patent information of a drug in the patent list pursuant to paragraph (1), shall submit an application for registration, stating the following matters, to the Minister of Food and Drug Safety by attaching the copy of the patent register, the written consent of a patentee or exclusive licensee under the Patent Act (hereinafter referred to as “patentee, etc.”), and other documents prescribed by Ordinance of the Prime Minister, within 30 days from the date of marketing approval or revised approval or from the date of registration of the patent pursuant to Article 87 of the Patent Act:

1. Name of a drug;
2. Personal information of a registration applicant;
3. Personal information of a patentee, etc. (where a patentee does not reside or have a place of business within Korea, referring to the personal information of a representative of the patentee who resides or has a place of business within Korea);
4. Patent number;
5. Expiration date of a patent;
6. Claim to be protected (hereinafter referred to as "claim");
7. Other matters prescribed by Ordinance of the Prime Minister.

(3) A person, who has filed an application for registration of the patent information of a drug pursuant to paragraph (1), may file an application for changing the details of a registration application specified in

paragraph (2) before the decision on the application is made: Provided, That in cases of adding claims, he/she shall file an application within the period for application referred to in paragraph (2).

(4) Where the drug patent, for which registration has been applied pursuant to paragraph (1) or the change of the registration application has been applied pursuant to paragraph (3), meets all of the following subject matters and requirements, the Minister of Food and Drug Safety shall register in the patent list the matters prescribed by Ordinance of the Prime Minister, such as the drug name, personal information of the patentee, etc., the patent registration number, and the expiration date of the patent, and post them on the Internet homepage for the public:

1. Falling under any of the following:
2. Being directly related to the approved matters of the relevant drug;
3. Being filed pursuant to Article 42 of the Patent Act before marketing approval or revised approval of the relevant drug is granted;
4. Not having expired by the expiration of the duration of the patent, becoming invalid, relinquishment, etc.;
5. Having marketing approval or revised approval of the relevant drug.

(5) Where it is necessary to review whether to meet the subject matters and requirements referred to in paragraph (4), the Minister of Food and Drug Safety may order a person filing an application for registration of a drug patent to submit additional data.

(6) Matters necessary for procedures, methods, etc. of filing applications for registration of drug patents pursuant to paragraph (1) or applications for changing the details of registration applications pursuant to paragraph (3) shall be prescribed by Ordinance of the Prime Minister.

Article 50-3 (Change, Etc. of Registered Information)

(1) A person, who has registered the patent information of a drug in the patent list after filing an application for registration of a drug patent pursuant to Article 50-2 (1) (hereinafter referred to as “registered patentee”), may file an application for the change or deletion of the patent information registered in the patent list pursuant to Article 50-2 (4) (hereinafter referred to as “registered information”) with the Minister of Food and Drug Safety.

(2) An application for the change of the expiration date of a patent registered in the patent list (hereinafter referred to as “registered patent”) among the registered information shall be filed within 30 days from the date of such change: Provided, That the Minister of Food and Drug Safety may grant a further period of up to 30 days for the change upon application of the registered patentee.

(3) The Minister of Food and Drug Safety may change or delete the registered information if an application filed under paragraph (1) is appropriate after verifying it. In such cases, the Minister of Food and Drug Safety shall in advance seek the opinions of interested persons, such as a patentee of a drug (hereinafter referred to as “patentee, etc. of a listed drug”), the patent information of which is registered in the patent list (hereinafter referred to as "listed drug") or a person who has filed an application for marketing approval or revised approval of a drug, based on the safety and efficacy information of a listed

drug.

(4) In any of the following cases, the Minister of Food and Drug Safety may change or delete, ex officio, the registered information. In such cases, the Minister of Food and Drug Safety shall seek the opinions of the registered patentee in advance:

1. Where the patentee, etc. withdraws his/her consent;
2. Where the subject matters and requirements of Article 50-2 (4) cease to be met;
3. Where the patent of a drug is registered deceitfully or otherwise fraudulently.

(5) Where the Minister of Food and Drug Safety changes or deletes the registered information pursuant to paragraphs (3) and (4), he/she shall post them on the Internet homepage for the public.

(6) Matters necessary for procedures, methods, etc. of filing applications for the change or deletion of the registered information pursuant paragraph (1) shall be prescribed by Ordinance of the Prime Minister.

Article 50-4 (Notice of Application for Marketing Approval, etc.)

(1) Each person, who has filed an application for marketing approval of a drug pursuant to Article 31 (2) or (3) based on the information on safety and efficacy of a listed drug, or who has filed an application for approval of the change of the efficacy and effectiveness pursuant to paragraph (9) of the same Article, shall notify the registered patentee and patentee, etc. of a listed drug of the matters prescribed by Ordinance of the Prime Minister, such as the fact that the application for marketing approval has been filed and the filing date of the application: Provided, That this shall not apply in any of the following cases:

1. Where the period of a registered patent expires;
2. Where an application for approval or revised approval of a drug is filed to market the drug after the period of a registered patent expires;
3. Where a registered patentee and a patentee, etc. of a listed drug express their consent for the exemption from providing notice;
4. Cases prescribed by Presidential Decree, corresponding to subparagraphs 1 through 3.

(2) Notwithstanding paragraph (1), if the causes referred to in paragraph 1 (2) through (4) cease to exist, a notice shall be given under the main sentence of paragraph (1).

(3) A notice referred to in paragraph (1) or (2) shall be deemed to be given when the notice arrives at the domestic domicile of the patentee, etc. or his/her representative stated in the patent list.

(4) A notice referred to in paragraph (1) or (2) shall be given within 20 days from the date an application for marketing approval or revised approval is filed. If the notice is not given within such period, the date on which a person, who has filed an application for marketing approval or revised approval, gives notice to a registered patentee or a patentee, etc. of a listed drug, whichever occurs later, shall be deemed to be the filing date of an application for marketing approval or revised approval.

(5) Each person, who has given notice pursuant to paragraph (1) or (2), shall without delay submit a document evidencing such notice to the Minister of Food and Drug Safety. In such cases, the Minister of Food and Drug Safety shall post the matters prescribed by Ordinance of the Prime Minister, such as the

filing date of an application for marketing approval, main ingredients, dosage form, etc. of the notified drug (hereinafter referred to as "notified drug") on the Internet homepage for the public.

(6) Where notice referred to in paragraph (1) or (2) is not given, the Minister of Food and Drug Safety shall not grant the relevant marketing approval or revised approval.

(7) Matters necessary for the method, procedure, etc. of giving notice under paragraph (1) shall be prescribed by Ordinance of the Prime Minister.

Article 50-5 (Application for Prevention of Marketing)

(1) A patentee, etc. of a listed drug may file an application for the prevention of marketing of the notified drug with the Minister of Food and Drug Safety by attaching the statement including the following, within 45 days from the date of receipt of notice pursuant to Article 50-4:

1. An application for marketing prevention shall have been filed based on the patent registered lawfully;
2. A petition for trial or litigation referred to in paragraph (2) shall have been filed in good faith, there is a prospect of winning a case, and the trial or litigation shall not be delayed unreasonably.

(2) A patentee, etc. of a listed drug shall institute any of the following patent-related litigations or file or take a petition for any of the following patent-related trials before he/she files an application for marketing prevention:

1. A litigation to seek injunction for, or prevention of infringement of patent rights pursuant to Article 126 of the Patent Act;
2. A trial to confirm the scope of patent rights pursuant to Article 135 of the Patent Act.

(3) Notwithstanding paragraph (1), an application for marketing prevention of the drug whose marketing has already been prevented pursuant to Article 50-6 (1) shall not be additionally filed: Provided, That this shall not apply to an application for marketing prevention of a drug notified after an application for the change of efficacy and effectiveness is filed pursuant to Article 31 (9).

(4) The Minister of Food and Drug Safety shall not grant marketing approval or revised approval of the notified drug until the period for filing an application for marketing prevention under paragraph (1) expires: Provided, That this shall not apply in any of the following cases:

1. Where there is a trial ruling pursuant to Article 162 of the Patent Act or a ruling pursuant to Article 189 of the same Act that the drug for which marketing prevention was applied does not fall within the scope of registered patent rights;
2. Where there is a trial ruling pursuant to Article 162 of the Patent Act or a ruling pursuant to Article 189 of the same Act that the registered patent is invalid;
3. Where there is a decision pursuant to Article 43 of the Administrative Appeals Act and a ruling of a court against a litigation instituted pursuant to Article 3 of the Administrative Litigation Act that registration of a drug patent is illegal.

(5) Where there is a court ruling or ruling against the trial ruling, decision or ruling pursuant to each subparagraph of paragraph (4) after such trial ruling, decision or ruling, the Minister of Food and Drug Safety shall not grant marketing approval or revised approval for the notified drug, notwithstanding the

proviso to paragraph (4).

(6) Matters necessary for the method, procedure, etc. of filing applications for marketing prevention shall be prescribed by Ordinance of the Prime Minister.

Article 50-6 (Marketing Prevention, Etc.)

(1) Where the Minister of Food and Drug Safety in receipt of an application for marketing prevention under Article 50-5 (1) grants marketing approval or revised approval for the drug for which the application for marketing prevention was filed, he/she shall prevent the marketing of such drug for nine months from the date when the patentee, etc. of a listed drug is notified pursuant to Article 50-4 (hereinafter referred to as "date of receipt of notice"), except in any of the following cases:

1. Where the application is filed after the filing period referred to in Article 50-5 (1) expires;

2. Where the application is filed, based on the patent which have expired by the expiration of the patent, relinquishment, etc.;

3. Where the application is filed without having instituted a litigation or having filed or taken a petition for trial pursuant to each subparagraph of Article 50-5 (2);

4. Where a drug patent is registered deceitfully or otherwise fraudulently;

5. Where at least two drugs are notified under Article 50-4 and the application for marketing prevention is filed only for some of the drugs, of which the following matters are same with those of the notified drugs (hereinafter referred to as "same drug"):

(a) Main ingredients and the amount thereof;

(b) Dosage form;

(c) Usage and dosage;

(d) Efficacy and effectiveness;

6. Where the same drug with the drug, for which the application for marketing prevention is filed, has already been approved for marketing, based on the information on safety and efficacy of the listed drug;

7. Where a trial ruling, decision or ruling falling under Article 50-5 (4) is made;

8. Where a registered patent becomes falling under Article 106 (1) or 106-2 (1) of the Patent Act or is subject to a petition for adjudication pursuant to Article 107 of the same Act.

(2) Where a trial ruling or ruling (including a ruling for retrial made under Article 178 of the Patent Act) to revoke or reverse the trial ruling, decision or ruling referred to in paragraph (1) 7 becomes final and conclusive before granting marketing approval or revised approval of the notified drug, the Minister of Food and Drug Safety shall prevent the marketing of such drug for nine months from the date of receipt of notice, notwithstanding paragraph (1).

(3) Marketing prevention referred to in paragraph (1) shall remain in effect until one of the following dates, whichever comes first:

1. The date a trial ruling or ruling is made that the drug for which the application for marketing prevention has been filed does not fall within the scope of rights of the registered patent;

2. The date a trial ruling is made that the drug for which the application for marketing prevention has been filed does not infringe the registered patent;

3. The date a trial ruling or ruling is made that the registered patent is invalid;

4. The date a decision or ruling is made that the registration of the drug patent is illegal;

5. The date a trial or litigation referred to in Article 50-5 (2) ended by the withdrawal or consent of withdrawal of a patentee, etc., reconciliation, rejection, etc.;

6. The date the arbitration or mediation regarding a trial or litigation referred to in Article 50-5 (2) is completed;

7. The date the period for marketing approval or revised approval of the listed drug expires;

8. The expiration date of the registered patent;

9. The date a resolution by the Fair Trade Commission or a trial ruling by a court is made that a registered patentee, etc. has violated the provisions of Article 3-2 (1), 19 (1) or 23 (1) of the Monopoly Regulation and Fair Trade Act in connection with marketing prevention or exclusive marketing approval referred to in Article 50-7;

10. The date it is found that the application for marketing prevention has been filed by fraudulent or other wrongful means.

(4) Matters necessary for marketing prevention, procedure of extinction, etc. pursuant to paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

Article 50-7 (Application for Exclusive Marketing Approval)

(1) Where a person, who shall notify pursuant to Article 50-4, files an application for marketing approval or revised approval of a drug, he/she may also file an application for exclusive marketing approval of the drug with the Minister of Food and Drug Safety, prior to the marketing of drugs meeting all of the following requirements (hereinafter referred to as “exclusive marketing approval”):

1. To be the same drug with the drug for which an application for exclusive marketing approval is filed;

2. To be the drug, the effective ingredients of which are identical to those of the listed drug, among the drugs for which an application for marketing approval or revised approval has been filed, based on safety and efficacy information of the listed drug.

(2) Each person, who intends to obtain exclusive marketing approval, shall file a petition for any of the following trials:

1. A trial on invalidity of a patent pursuant to Article 133 of the Patent Act;

2. A trial to invalidate registration for extension of a patent pursuant to Article 134 of the Patent Act;

3. A trial to confirm scope of rights pursuant to Article 135 of the Patent Act.

(3) Each person, who files a petition for a trial under paragraph (2), shall without delay notify the Minister of Food and Drug Safety of the matters prescribed by Ordinance of the Prime Minister, such as the number of the patent trial. The Minister of Food and Drug Safety may post the matters notified on the Internet homepage for the public.

(4) Each person, who intends to obtain exclusive marketing approval, shall submit an application for exclusive marketing approval, stating the following matters, to the Minister of Food and Drug Safety, by attaching the documents prescribed by Ordinance of the Prime Minister such as a petition for trial:

1. Personal information of an applicant;
2. Patent registration number;
3. Patent trial number;
4. Filing date of a petition for trial;
5. Other matters prescribed by Ordinance of the Prime Minister.

Article 50-8 (Exclusive Marketing Approval)

(1) Upon receipt of an application for exclusive marketing approval pursuant to Article 50-7, the Minister of Food and Drug Safety shall grant exclusive marketing approval together with marketing approval or revised approval of a drug, when the applicant meets all of the following requirements:

1. He/she shall be the first applicant among those who have filed an application for marketing approval or revised approval of the drug to be notified pursuant to Article 50-4 (where several persons have filed applications on the same day, the same priority shall be given to all of them);
2. He/she shall file a petition for a trial under Article 50-7 (2), and then receive a trial ruling or ruling that the registered patent is invalid, the registration for extension of the registered patent is invalid. or the relevant drug does not fall in the scope of the registered patent: Provided, That a person who received a trial ruling or ruling after nine months have passed from the date of receipt of notice is excluded therefrom;
3. He/she shall meet one of the following requirements and receive a trial ruling or ruling pursuant to subparagraph (2):

(2) Where the Minister of Food and Drug Safety grants exclusive marketing approval pursuant to paragraph (1), he/she shall post the matters prescribed by Ordinance of the Prime Minister, such as the main ingredient or formulation of the drug approved for exclusive marketing, or the date of approval, on the Internet homepage for the public.

Article 50-9 (Marketing Prevention, Etc. of Same Drugs, Etc.)

(1) Where the Minister of Food and Drug Safety grants exclusive marketing approval of a drug pursuant to Article 50-8 (1), he/she may prevent the marketing of the drugs meeting all of the following requirements during the period referred to in paragraph (2), granting marketing approval or revised approval for such drugs:

1. To be the same drug with the drug approved for exclusive marketing;
2. To be the drug, the effective ingredients of which are identical to those of the listed drug, among the drugs for which an application for marketing approval or revised approval has been filed, based on safety and efficacy information of the listed drug.

(2) The period of marketing prevention under paragraph (1) shall be nine months from the date a person who has obtained first exclusive marketing approval of a drug may sell the drug: Provided, That in cases

of a drug for which an application for the medical care benefits has been filed pursuant to Article 41 (1) 2 of the National Health Insurance Act, it may be extended by up to two months.

(3) Matters necessary for the method, procedure, etc. of marketing prevention referred to in paragraphs (1) and (2) shall be prescribed by Ordinance of the Prime Minister.

Article 50-10 (Extinction of Effect of Marketing Prevention of Same Drug, Etc.)

(1) Marketing prevention referred to in Article 50-9 (1) shall cease to have effect on any of the following dates, whichever comes earlier:

1. The date marketing approval or revised approval of a drug approved for exclusive marketing, does not have effect;

2. The date a registered patent does not have effect due to the expiration of the registered patent or the finalizations, etc. of a trial ruling or ruling that the registered patent is invalid (excluding the petition for a trial or litigation filed by the person who has obtained exclusive marketing approval).

(2) The Minister of Food and Drug Safety shall terminate the effect of marketing prevention under Article 50-9 (1) in any of the following cases. In such cases, the Minister of Food and Drug Safety shall consider the opinions of the person who has obtained exclusive marketing approval in advance:

1. Where a ruling to cancel or reverse a trial ruling or ruling referred to in Article 50-8 (1) 2 is made (including a ruling for retrial referred to in Article 178 of the Patent Act);

2. Where the marketing of the drug approved for exclusive marketing is delayed for two months from the date the marketing becomes feasible, without just cause;

3. Where a resolution by the Fair Trade Commission or a trial ruling by a court is made that a person who has obtained exclusive marketing approval violates Articles 3-2 (1), 19 (1) or 23 (1) of the Monopoly Regulation and Fair Trade Act in connection with marketing prevention or exclusive marketing approval;

4. Where a person has obtained exclusive marketing approval deceitfully or otherwise fraudulently.

(3) Any person who has filed an application for marketing approval or revised approval of the same drug with those approved for exclusive marketing or any other interested party, may provide the information that exclusive marketing approval falls under paragraph (1) or (2) to the Minister of Food and Drug Safety.

(4) Matters necessary for the extinction of the effect of marketing prevention, the method, procedure, etc. of the provision of information by the interested persons pursuant to paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

Article 50-11 (Impact Assessment)

(1) The Minister of Food and Drug Safety shall analyze and assess the impact of the matters prescribed in this Chapter, such as marketing prevention and exclusive marketing approval under Article 50-6, on the domestic pharmaceutical industry, health policies, fluctuations of employment, etc.

(2) Where deemed necessary for the impact assessment referred to in paragraph (1), the Minister of Food and Drug Safety may request the relevant administrative agency, education and research institution, etc. to

provide necessary data. In such cases, the head of the relevant administrative agency, education and research institution, etc. in receipt of the request for the provision of data, shall comply therewith, except in extenuating circumstances.

(3) Where the impact assessment is conducted pursuant to paragraph (1), overseas cases shall be analyzed.

(4) The Minister of Food and Drug Safety shall disclose the result of the impact assessment conducted under paragraph (1), and report it to the National Assembly.

(5) Matters necessary for the standard, method, procedure, etc. of the impact assessment referred to in paragraphs (1) through (4) shall be prescribed by Ordinance of the Prime Minister.

Article 50-12 (Management, etc. of Listed Drugs)

(1) The Minister of Food and Drug Safety shall implement the following business regarding drug patents:

1. Collecting information on market trends and prices of listed drugs;
2. Supporting small and medium enterprises to conduct affairs regarding registration in the patent list, exclusive marketing approval, etc.;
3. Providing training to pharmaceutical companies to enhance their competency related to drug patents;
4. Analyzing and providing patent information on listed drugs;
5. Researching overseas cases and policies regarding the matters prescribed in this Chapter, and producing and analyzing statistics thereof;
6. Other business deemed necessary by the Minister of Food and Drug Safety.

(2) The Minister of Food and Drug Safety may entrust the implementation of the business referred to in paragraph (1) to other institutions.

(3) Where deemed necessary to implement the business referred to in paragraph (1), the Minister of Food and Drug Safety may request any of the following institutions to provide data regarding drug patents, etc., and the institutions in receipt of such request shall comply therewith, except in extenuating circumstances:

1. The State or local governments;
2. Public institutions or public organizations.

Article 51 (Korean Pharmacopoeia)

(1) In order to ensure the appropriateness in the nature, state, quality, and storing method of drugs, etc., and similar matters, the Minister of Food and Drug Safety shall enact the Korean Pharmacopoeia following deliberation by the Central Pharmaceutical Affairs Council, and shall announce it publicly. *<Amended by Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>*

(2) The Korean Pharmacopoeia shall consist of Parts I and II: drug substances that are frequently used and the primary preparations shall be mainly listed in Part I, and the mixed preparations of drugs and the drugs, etc. not listed in Part I shall be mainly listed in Part II. *<Amended by Act No. 10788, Jun. 7, 2011>*

Article 52 (Standards for Drugs, etc.)

(1) With regard to biological preparations and drugs which are not listed in the Korean Pharmacopoeia, the Minister of Food and Drug Safety may, after consultation with the Central Pharmaceutical Affairs Council, determine the nature, state, quality and storing methods, and other necessary standards therefor.

<Amended by Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>

(2) Where the Minister of Food and Drug Safety deems it necessary to prevent any danger or harm to the public health and sanitation, he/she may, after consultation with the Central Pharmaceutical Affairs Council, determine the manufacturing method, nature, efficacy, quality, and storing method of quasi-drugs and other necessary standards therefor. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 52-2 (Surveys, Research, etc. on Actual Status of Safe Use of Drugs by Specific Groups)

(1) The Minister of Health and Welfare and the Minister of Food and Drug Safety may survey the actual status of safe use of drugs by a group prescribed by Ordinance of the Prime Minister, which requires special attention, such as seniors, children, or pregnant women (hereinafter referred to as "specific group"), as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) For the survey referred to in paragraph (1), the Minister of Food and Drug Safety may instruct the manufacturers of the relevant drugs or the persons who have obtained marketing approval of the relevant drugs to investigate and research the impact of such drugs on the relevant specific group. In such cases, the manufacturers or persons who have obtained marketing approval, in receipt of such instruction, shall comply therewith.

Article 53 (Drugs under National Lot Release)

(1) A person who intends to sell or to display, keep, or store, for sale, the drugs prescribed by Ordinance of the Prime Minister, among the following drugs, shall obtain lot release approval from the Minister of Food and Drug Safety after the data on manufacturing and quality control of the drugs is examined and inspected: *<Amended by Act No. 11690, Mar. 23, 2013>*

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

(2) Matters necessary for the procedures and methods for lot release approval under paragraph (1) and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 54 (Radiopharmaceuticals)

The Minister of Food and Drug Safety may determine matters necessary for manufacturing and importation of radiopharmaceuticals after consultation with the Minister of Science, ICT and Future Planning. *<Amended by Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>*

Article 55 (Addictive and Habit-forming Drugs)

Matters necessary for the manufacturing and management of drugs that might affect the human body and thus lead to addiction or habit-forming, shall be prescribed by a separate Act.

Article 56 (Labelling of Drug Containers, etc.)

(1) A person who has obtained marketing approval and an importer shall indicate the following information on the containers or packages of drugs: Provided, That in cases of the containers or packages prescribed by Ordinance of the Prime Minister, some of the following information may be omitted or only

some of the following information may be indicated, as prescribed by Ordinance of the Prime Minister: *<Amended by Act No. 11421, May 14, 2012; Act No. 11690, Mar. 23, 2013>*

1. Trade name and address of a person who has obtained marketing approval of drugs or an importer (in cases of contract manufacturing business, trade name and address of a factory shall be included);
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 articles;
5. Mandatory information in labels of containers or packages prescribed by the Korean Pharmacopoeia;
6. As for drugs, the standards for which are determined under Article 52 (1), the storing methods and mandatory information in labels of the containers or packages of such drugs in accordance with such standards;
7. As for drugs not listed in the Korean Pharmacopoeia, names of active ingredients (if general names exist, such names shall be indicated) and quantity (if active ingredients are not clear, the essence thereof and outline of manufacturing methods shall be indicated);
8. Letters of "prescription drug" or "over-the-counter drug" *[in cases of safe and readily available drugs, letters of "over-the-counter (safe and readily available) drugs];*
9. Information provided for in subparagraphs 1 through 3 of Article 58;
10. Other information prescribed by Ordinance of the Prime Minister.

(2) A person who sells drugs directly to consumers, such as a pharmacy founder, shall indicate prices of drugs on the containers or packages of such drugs, as prescribed by the Minister of Health and Welfare.

Article 56 (Labelling of Drug Containers, etc.)

(1) A person who has obtained marketing approval and an importer shall indicate the following information on the containers or packages of drugs: Provided, That in cases of the containers or packages prescribed by Ordinance of the Prime Minister, some of the following information may be omitted or only some of the following information may be indicated, as prescribed by Ordinance of the Prime Minister: *<Amended by Act No. 11421, May 14, 2012; Act No. 11690, Mar. 23, 2013; Act No. 14328, Dec. 2, 2016>*

1. Trade name and address of a person who has obtained marketing approval of drugs or an importer (in cases of contract manufacturing business, trade name and address of a factory shall be included);
2. Product name;
3. Manufacturing number and effective period or time-limit for use;
4. Weight, capacity, or number of articles;
5. Mandatory information in labels of containers or packages prescribed by the Korean Pharmacopoeia;
6. As for drugs, the standards for which are determined under Article 52 (1), the storing methods and mandatory information in labels of the containers or packages of such drugs in accordance with such standards;

7. The name of all ingredients, quantity of active ingredients (if active ingredients are not clear, referring to the essence thereof and outline of manufacturing methods), and quantity of preservatives stated in the certificate of marketing approval and certificate of marketing notification: Provided, That ingredients prescribed by Ordinance of the Prime Minister, such as ingredients included in small quantity except preservatives, may be excluded;

8. Letters of "prescription drug" or "over-the-counter drug" *[in cases of safe and readily available drugs, letters of "over-the-counter (safe and readily available) drugs];*

9. Information provided for in subparagraphs 1 through 3 of Article 58;

10. Other information prescribed by Ordinance of the Prime Minister.

(2) A person who sells drugs directly to consumers, such as a pharmacy founder, shall indicate prices of drugs on the containers or packages of such drugs, as prescribed by the Minister of Health and Welfare.

Article 57 (Labelling of Outside Packages)

If information listed in subparagraphs of Articles 56 (1) and 56 (2), which have been indicated on the immediate container or package of drugs, are not visible because it is obstructed by the outside container or package, such information shall also be indicated on the outside container or package. *<Amended by Act No. 10788, Jun. 7, 2011>*

Article 58 (Information in Package Inserts)

The following information shall be indicated in package inserts for drugs: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>*

1. Directions, doses, and other precautions necessary for use or handling;

2. As for drugs listed in the Korean Pharmacopoeia, mandatory information in package inserts for drugs or labels of containers or packages of drugs provided for in the Korean Pharmacopoeia;

3. As for drugs, the standards for which are determined under Article 52 (1), mandatory information in package inserts for drugs or labels of containers or packages of drugs in accordance with such standards;

4. Other information prescribed by Ordinance of the Prime Minister.

Article 59 (Precautions in Indications)

Information provided for in Articles 56 though 58 shall be indicated on places which are more easily seen than other letters, news articles, pictures or designs, and such information shall be indicated precisely in easy and understandable terms, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

Article 60 (Information Prohibited from being Indicated)

Any of the following information shall not be indicated in package inserts for drugs or labels of containers or packages of drugs: *<Amended by Act No. 8643, Oct. 17, 2007>*

1. False or misleading information with regard to the relevant drug;

2. Efficacy or effectiveness 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 followings drugs for sale: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011>*

1. Drugs in violation 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 indicate information that leads to misunderstandings about medical efficacy, effectiveness, etc. in containers, packages, or package inserts for articles, other than drugs, shall advertise such information, or shall sell, store or display for sale, articles in which such information is indicated or advertised.

Article 62 (Prohibition of Manufacturing, etc.)

No one shall sell any of the following drugs nor shall manufacture, import, store, or display them for sales purposes: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>*

1. Drugs which are listed in the Korean Pharmacopoeia, but whose nature, efficacy or quality does not meet standards specified in the Korean Pharmacopoeia;
2. Drugs which are licensed 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 contents as licensed or reported;
3. Drugs the standards for which 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 germs that may cause a disease;
6. Drugs to which alien substances are mixed or adhered;
7. Drugs in which tar pigment other than that determined by the Minister of Food and Drug Safety is used;
8. Drugs which are manufactured under unsanitary circumstances that might cause harm to public health and sanitation, or which are manufactured at a place where the manufacturing equipment fails to meet the standards prescribed by Presidential Decree;
9. Drugs which are deemed to cause harm to the public health and sanitation, due to 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 marketing approval, or an importer 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 Prime Minister: Provided, That this shall not apply where he/she sells them to a drug

manufacturer, or a person who has obtained marketing approval. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

Article 64 (Safety Containers or Packages, etc.)

(1) Where a person who has obtained marketing approval or an importer 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: Provided, That the same shall not apply where they are sold to drug manufacturers or persons who have obtained marketing approval. *<Amended by Act No. 8643, Oct. 17, 2007>*

(2) The scope of products for which safety containers or packages shall be used and the criteria, etc. for safety containers or packages shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

Article 65 (Labelling of Containers, etc. of Quasi-Drugs)

(1) A manufacturer and importer of quasi-drugs shall indicate the following information in the containers, packages, or package inserts (if any) for quasi-drugs: Provided, That in cases of the containers or packages designated by Ordinance of the Prime Minister, only the names of quasi-drugs and the trade names of manufacturers or importers may be stated: *<Amended by Act No. 11690, Mar. 23, 2013>*

1. Names of quasi-drugs (excluding products under subparagraph 7 (a) of Article 2);
2. Trade 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. Manufacturing number and date (referring to the period of use, instead of the manufacturing number and date, in cases of products under subparagraph 7 (b) of Article 2);
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 storing methods and mandatory information in containers or packages under such standards;
7. The letter "quasi-drug";
8. Other information prescribed by Ordinance of the Prime Minister.

(2) A person who sells quasi-drugs directly to consumers, such as a pharmacy founder, shall indicate prices of quasi-drugs on their containers or packages, as prescribed by the Minister of Health and Welfare.

Article 65 (Labelling of Containers, etc. of Quasi-Drugs)

(1) A manufacturer and importer of quasi-drugs shall indicate the following information in the containers, packages, or package inserts (if any) for quasi-drugs: Provided, That some of the following matters may not be stated or only some of the following matters may be stated, as prescribed by Ordinance of the Prime Minister: *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 14328, Dec. 2, 2016>*

1. Names of quasi-drugs (excluding products under subparagraph 7 (a) of Article 2);
2. Trade 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. Manufacturing number and date (referring to the period of use, instead of the manufacturing number and date, in cases of products under subparagraph 7 (b) of Article 2);

5. The name of all ingredients stated in the certificate of marketing approval and certificate of marketing notification (excluding products under subparagraph 7 (a) of Article 2): Provided, That ingredients prescribed by Ordinance of the Prime Minister, such as ingredients included in small quantity except preservatives, may be excluded;

6. For products, the standards for which are determined under Article 52 (2), the storing methods and mandatory information in containers or packages under such standards;

7. The letter "quasi-drug";

8. Other information prescribed by Ordinance of the Prime Minister.

(2) A person who sells quasi-drugs directly to consumers, such as a pharmacy founder, shall indicate prices of quasi-drugs on their containers or packages, as prescribed by the Minister of Health and Welfare.

Article 65-2 (Precautions in Indications)

Information provided for in Article 65 shall be indicated on places which are more easily seen thant other letters, articles, pictures or designs, and such information shall be indicated precisely in easy and understandable terms, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

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 among quasi-drugs) shall apply mutatis mutandis to quasi-drugs. In such cases, "drugs" shall be construed as "quasi-drugs", and "Article 31 (2) and (3)" as "Article 31 (4)". *<Amended by Act No. 11251, Feb. 1, 2012>*

Article 67 (Organization)

Drug manufacturers, etc., persons who have obtained marketing approval, importers, or drug distributors may incorporate an association, respectively, in order to ensure independent activities and common interests and to contribute to the improvement of the national public health. *<Amended by Act No. 8643, Oct. 17, 2007>*

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 news article shall be used for drugs to make people misunderstand that physicians, dentists, oriental medical doctors, 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 news 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 a license or submitting a report, under Article 31 (2) and (3) or 42 (1). *<Amended by Act No. 8643,*

Oct. 17, 2007>

(6) Matters necessary for the scope of advertisement of drugs and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

Article 68-2 (Deliberation of Advertisement)

(1) Where a drug manufacturer, a person who has obtained marketing approval, or an importer intends to advertise drugs manufactured or imported by himself/herself, he/she shall undergo deliberation by the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

(2) The Minister of Food and Drug Safety may entrust an association incorporated pursuant to Article 67 with affairs concerning deliberation on advertisement of drugs under paragraph (1). *<Amended by Act No. 11690, Mar. 23, 2013>*

(3) Procedure for and method of deliberation on advertisement under paragraph (1) and matters necessary for raising an objection against the results of deliberation, altering the details of deliberation, and indicting the results of deliberation shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>*

Article 68-3 (Establishment)

(1) The Korea Institute of Drug Safety and Risk Management (hereinafter referred to as the "'Institute of Drug Safety and Risk Management") shall be established to efficiently and systematically perform the duties of collecting, managing, analyzing, assessing, and supplying a variety of information on drug safety, such as side effects of drugs, etc., information on marketing approval, and information on marketing notification (hereinafter referred to as "drug safety information").

(2) The Institute of Drug Safety and Risk Management shall be a corporate entity.

(3) Except as otherwise provided for in this Act, the provisions concerning incorporated foundations under the Civil Act shall apply mutatis mutandis to the Institute of Drug Safety and Risk Management.

(4) Other matters necessary for the organization and operation of the Institute of Drug Safety and Risk Management shall be prescribed by Presidential Decree.

Article 68-4 (Projects)

The Institute of Drug Safety and Risk Management shall conduct the following projects commissioned by the Minister of Food and Drug Safety pursuant to Article 84 or other Acts and subordinate statutes; projects for the relief of harm from side effects of drugs commissioned pursuant to Article 86 (5); and for-profit projects prescribed by Presidential Decree with regard to drug safety information: *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 12450, Mar. 18, 2014; Act No. 13320, May 18, 2015>*

1. Investigating and identifying causal relationships of side effects of drugs, such as pharmaceutical mishaps;

2. Establishing a drug safety information management system to gather and manage drug safety information;

3. Collecting, analyzing, assessing, managing, and supplying drug safety information;

4. Conducting investigation, research, education, and publicity aimed at developing and utilizing drug safety information;

5. Other projects commissioned under this Act or other Acts and subordinate statutes.

Article 68-5 (Financial Resources for Operation)

The Institute of Drug Safety and Risk Management shall be operated by contributions from the Government and persons, other than the Government, and other gains.

Article 68-6 (Submission, etc. of Business Plans)

(1) The business year of the Institute of Drug Safety and Risk Management shall coincide with the fiscal year of the Government.

(2) The Institute of Drug Safety and Risk Management shall prepare a business plan and budget bill for each fiscal year, as prescribed by Presidential Decree, and obtain approval from the Minister of Food and Drug Safety. The same shall apply to revisions to such business plan and budget bill. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 68-7 (Requests for Provision of Data)

(1) If deemed necessary for performing the duties, such as collection and assessment of drug safety information, the president of the Institute of Drug Safety and Risk Management may require any of the following institutions or persons to provide data regarding drug safety information. In such cases, an institution or a person, in receipt of a request, shall comply with such request, except in extenuating circumstances: *<Amended by Act No. 13114, Jan. 28, 2015>*

1. The State or a local government;

2. A public institution or public organization;

3. A research institute;

4. A pharmacy founder or a medical institution founder;

5. A person who may handle drugs in accordance with this Act, including a manufacturer of drugs, etc., a person who has obtained marketing approval of a drug, an importer, or a drug distributor.

(2) Where the president of the Institute of Drug Safety and Risk Management makes a request to provide necessary data pursuant to paragraph (1), he/she may request the provision of data including personal information, such as sensitive information prescribed in Article 23 of the Personal Information Protection Act, personally identifiable information (including resident registration numbers) prescribed in Article 24 of the same Act, etc. In such cases, the institution or person, in receipt of such request, shall provide data after deleting the parts by which individual identification is possible. *<Amended by Act No. 13114, Jan. 28, 2015>*

(3) Notwithstanding paragraph (2), where the Minister of Food and Drug Safety deems it necessary for analysis for the president of the Institute of Drug Safety and Risk Management to combine data possessed by multiple number of institutions and persons, the president may collect data including the parts by which individual identification is possible for the combination of data. In such cases, the president shall, with

delay, redact the parts by which personal identification is possible after the combination of data, and he/she shall take measures so that the deleted parts are not to be restored or regenerated. *<Newly Inserted by Act No. 13114, Jan. 28, 2015>*

(4) No data provided pursuant to paragraphs (1) through (3) shall be used for any purpose other than a request. *<Newly Inserted by Act No. 13114, Jan. 28, 2015>*

(5) The Minister of Food and Drug Safety may regularly examine whether the president of the Institute of Drug Safety and Risk Management complies with paragraphs (3) and (4) and take necessary measures, such as dismissal, etc., if he/she fails to comply with the paragraphs. *<Newly Inserted by Act No. 13114, Jan. 28, 2015>*

Article 68-8 (Reporting Side Effects, etc.)

(1) Where a manufacturer of drugs, etc., a person who has obtained marketing approval of drugs, an importer, or a drug wholesaler becomes aware of an adverse event suspected of having been caused by drugs, etc. such as a disease, disability, death, or other event relating to the safety and effectiveness of other drugs, etc. prescribed by Ordinance of the Prime Minister, he/she shall report thereon to the president of the Institute of Drug Safety and Risk Management, as prescribed by the Minister of Food and Drug Safety. *<Amended by Act No. 11690, Mar. 23, 2013>*

(2) Where a pharmacy founder and a medical institution founder becomes aware of an adverse event suspected of having been caused by drugs, etc. such as a serious disease, disability, and death prescribed by Ordinance of the Prime Minister, he/she shall report thereon to the president of the Institute of Drug Safety and Risk Management, as prescribed by the Minister of Food and Drug Safety. *<Amended by Act No. 11690, Mar. 23, 2013>*

(3) The president of the Institute of Drug Safety and Risk Management shall report to the Minister of Food and Drug Safety the matters on which he/she has received a report under paragraphs (1) and (2), as prescribed by the Minister of Food and Drug Safety. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 68-9 (Duty of Confidentiality)

No person who is or was an executive or employee of the Institute of Drug Safety and Risk Management shall divulge any confidential information he/she has become aware of in the course of performing his/her duties.

Article 68-10 (Prohibition against Use of Similar Names)

Any person, other than the Institute of Drug Safety and Risk Management, shall be prohibited from using the name “the Institute of Drug Safety and Risk Management” or any other similar name.

Article 68-11 (Establishment of Deliberative Council on Side Effects of Drugs)

(1) In order to deliberate on the following matters, the Deliberative Council on Side Effects of Drugs (hereinafter referred to as the "Deliberative Council") shall be established under the jurisdiction of the Ministry of Food and Drug Safety: *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 12450, Mar. 18, 2014>*

1. Matters concerning judgment of side effects and likelihood of hazards of drugs, etc.;

2. Matters concerning identifying the causal relationship of side effects of drugs, etc. and identifying the causes of pharmaceutical mishaps, etc.;

3. Matters concerning relieving harm caused by drugs, such as benefits for relief of harm, etc. under Article 86-3 (1).

(2) The Deliberative Council shall be comprised of 10 to 15 members, including one chairperson, and the chairperson shall be elected by and from among its members.

(3) The members shall be appointed or commissioned by the Minister of Food and Drug Safety, as prescribed by Presidential Decree, including one person each from among the following persons: *<Amended by Act No. 11690, Mar. 23, 2013>*

1. An expert in public health care and drugs;

2. A person recommended by a non-profit, non-governmental organization prescribed in Article 2 of the Assistance for Non-Profit, Non-Governmental Organizations Act;

3. An expert prescribed in the Medical Service Act and forensic medicine who is qualified as a judge, prosecutor, or attorney-at-law;

4. A public official of a relevant central administration agency prescribed by Presidential Decree.

(4) Deleted. *<by Act No. 12450, Mar. 18, 2014>*

(5) The Deliberative Council may establish a working committee under its control to deliberate on matters prescribed in the subparagraphs of paragraph (1) from a professional perspective. *<Amended by Act No. 12450, Mar. 18, 2014>*

(6) Matters necessary for the organization and operation of the Deliberative Council and the working committee and other necessary matters shall be prescribed by Presidential Decree.

Article 68-12 (Drug Epidemiological Investigators)

(1) Where deemed necessary to perform the project prescribed in subparagraph 1 of Article 68-4, the president of the Institute of Drug Safety and Risk Management may appoint or commission an investigator for the epidemiological investigation of drugs (hereinafter referred to as "drug epidemiological investigator") from among employees of the Institute or persons with expertise and experience in the relevant field.

(2) When the president of the Institute of Drug Safety and Risk Management appoints or commissions a drug epidemiological investigator, he/she shall promptly report to the Minister of Food and Drug Safety.

(3) The president of the Institute of Drug Safety and Risk Management may have a drug epidemiological investigator enter a pharmacy, medical institution, and factory, warehouse, shop, or office in which drugs, etc. are manufactured, stored or handled, and other places deemed necessary for investigations to examine relevant books, documents, or other things, or make inquiries to interested persons about drugs, etc. In such cases, the drug epidemiological investigator shall carry a certificate indicating his/her authority and show it to interested persons. *<Amended by Act No. 13655, Dec. 29, 2015>*

(4) The qualifications and scope of duties of a drug epidemiological investigator and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

(5) The procedure, method, etc. of investigations or inquiries under paragraph (3) shall be prescribed by the Framework Act on Administrative Investigations, except as otherwise provided for in this Act or other Acts and subordinate statues concerning epidemiological investigations of drugs. *<Newly Inserted by Act No. 13655, Dec. 29, 2015>*

Article 69 (Reporting, Inspection, etc.)

(1) The Minister of Health and Welfare, the Minister of Food and Drug Safety, a Mayor/Do Governor, or the head of a Si/Gun/Gu may issue an order as follows: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013; Act No. 13219, Mar. 13, 2015>*

1. Directing that pharmacy founders; medical institution founders; manufacturers of drugs, etc.; persons who have obtained marketing approval of drugs; importers; distributors; persons who have obtained approval for protocols of clinical trials or biological equivalence tests; clinical trial institutions; biological equivalence test institutions; non-clinical trial institutions; and other persons engaged in handling drugs, etc. shall submit necessary documents or other data;

2. Directing that the relevant public officials shall visit pharmacies; medical institutions; factories; warehouses; shops or offices that manufacture, store, or handle drugs, etc.; clinical trial institutions; biological equivalence test institutions; non-clinical trial institutions; places where drugs, etc. are handled for clinical trials or biological equivalence tests; or other places where drugs, etc. are handled for business, to inspect the relevant facilities, relevant books and documents or other articles, or to inquire of the relevant persons;

3. Collecting drugs, etc. which are suspected to fall under Article 71 (1) or samples necessary for quality tests in a minimum quantity to the extent necessary for such test.

(2) Any public official who performs an inspection under paragraph (1) shall carry a certificate indicating such authority and produce it to the relevant persons. *<Amended by Act No. 13655, Dec. 29, 2015>*

(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 Prime Minister, following consultation with the Minister of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

(4) The procedure, method, etc. of inspections or inquiries under paragraph (1) 2 shall be prescribed by the Framework Act on Administrative Investigations, except as otherwise provided for in this Act. *<Newly Inserted by Act No. 13655, Dec. 29, 2015>*

Article 69-2 (Notification to Relevant Institution)

The Minister of Food and Drug Safety shall notify the head of the relevant central administrative agency prescribed by Presidential Decree of the following matters:

1. The disposition to prevent the marketing of drugs pursuant to Article 50-6 (1) and (2) and the extinction of the effect of marketing prevention under paragraph (3) of the same Article;

2. Exclusive marketing approval of drugs and the extinction of the effect of marketing prevention of the same drug under Article 50-10 (1) and (2);

3. Initiation and termination of a patent trial or litigation relevant to subparagraph 1 or 2.

Article 69-3 (Reporting on Matters of Agreement)

Where both parties agree as follows, they shall report the matters prescribed by Ordinance of the Prime Minister, such as the parties to the agreement, details of the agreement, and time of agreement, to the Minister of Food and Drug Safety and the Fair Trade Commission within 15 days from the date of conclusion of the agreement:

1. The agreement on the manufacturing or marketing of the notified drug between the person who has obtained marketing approval or revised approval of the listed drug or patentee, etc. of the listed drug and the person who has filed an application for marketing approval or revised approval of the notified drug;

2. The agreement on acquisition and extinction of exclusive marketing approval between the person who has obtained marketing approval or revised approval of the listed drug or patentee, etc. of the listed drug and the person who has filed an application for marketing approval or revised approval of the notified drug;

3. The agreement on acquisition and extinction of exclusive marketing approval among the persons who have filed an application for marketing approval or revised approval of the notified drug.

Article 69-4 (Correction Order)

Where pharmacy founders, persons who have obtained marketing approval of drugs, importers, drug distributors, and other persons entitled to market drugs under this Act fall under any of the following cases, the Minister of Health and Welfare, the Minister of Food and Drug Safety, or the head of the relevant Si/Gun/Gu may order them to correct such violation within a specified period: *<Amended by Act No. 14328, Dec. 2, 2016>*

1. Violation of matters necessary for management of a pharmacy pursuant to Article 21 (3);

2. Violation of matters necessary for the establishment of distribution systems of drugs, etc. and maintenance of order in distribution pursuant to Article 47 (1);

3. In cases of failing to prepare an expense report under Article 47-2 (1) or failing to retain the relevant expense report, books related thereto, or base data.

Article 70 (Order, etc. to Commence Business)

(1) If it is recognized that drug manufacturers, persons who have obtained marketing approval of drugs, pharmacy founders, or drug distributors cause or are likely to cause remarkable impediment in the purchase of drugs through joint suspension of manufacturing and marketing of drugs, or collective suspension or closure of business, the Minister of Health and Welfare, the Minister of Food and Drug Safety, a Mayor/Do Governor, or the head of a Si/Gun/Gu may order them to manufacture drugs or resume their business. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

(2) No drug manufacturer, person who has obtained marketing approval of drugs, pharmacy founder, or drug distributor shall refuse an order issued under paragraph (1) without just cause. *<Amended by Act No. 8643, Oct. 17, 2007>*

Article 71 (Order, etc. of Abandonment)

(1) The Minister of Food and Drug Safety, a Mayor/Do Governor, or the head of a Si/Gun/Gu may order persons who have obtained marketing approval of drugs, quasi-drug manufacturers, importers or distributors of drugs, etc., pharmacy founders, medical institution founders, or other persons prescribed by Ordinance of the Prime Minister among persons eligible to sell or handle drugs pursuant to this Act or other Acts to abandon the drugs, etc. which have been sold, stored, displayed, manufactured, or imported in violation of Articles 53 (1), 61 (including cases to which relevant provisions apply mutatis mutandis under Article 66), and 62 (including cases to which relevant provisions apply mutatis mutandis under 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; Act No. 11690, Mar. 23, 2013>*

(2) When any drug, etc. actually harms or is likely to harm public health, the Minister of Food and Drug Safety, a Mayor/Do Governor, or the head of a Si/Gun/Gu may order persons who have obtained marketing approval of drugs, quasi-drug manufacturers, importers or distributors of drugs, etc., pharmacy founders, medical institution founders, or other persons prescribed by Ordinance of the Prime Minister among persons eligible to sell or handle drugs pursuant to this Act or other Acts, to recall and abandon 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; Act No. 11690, Mar. 23, 2013>*

(3) Where any person in receipt of an order pursuant to paragraph (1) or (2) fails to comply with such order, or in cases of emergency for public health, the Minister of Food and Drug Safety, a Mayor/Do Governor, or the head of a Si/Gun/Gu may require relevant public officials to recall and abandon the relevant drug, etc., or to take other necessary measures. *<Amended by Act No. 11690, Mar. 23, 2013>*

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

(5) Necessary matters concerning the ranking of harms and standards for appraisal of drugs, etc., recall and abandonment of drugs, etc. and other measures under paragraph (2) shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

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

(1) When the Minister of Food and Drug Safety 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 marketing approval of drugs, quasi-drug manufacturers, or importers of drugs, etc. to publicly announce the recall plan: Provided, That he/she shall issue an order for public announcement if the use of a relevant drug, etc. causes harms prescribed by Ordinance of the Prime Minister, such as a serious side effect impossible to cure completely and a side effect temporarily or medically possible to cure completely. *<Amended by Act*

No. 8643, Oct. 17, 2007; Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013>

(2) Where the Minister of Food and Drug Safety, a Mayor/Do Governor, or the head of a Si/Gun/Gu has issued an order to recall and abandon drugs, etc. under distribution, or to take other necessary measures pursuant to Article 71 (2), he/she shall order persons who have obtained marketing approval of drugs, quasi-drug manufacturers, importers or distributors of drugs, etc., pharmacy founders, medical institution founders, or other persons prescribed by Ordinance of the Prime Minister from among persons eligible to sell or handle drugs pursuant to this Act or other Acts, to publicly announce such fact. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

(3) Each person in receipt of an order for public announcement under paragraphs (1) and (2) shall make a public announcement by any of the following methods, depending upon the ranking of harms under Article 71 (5): *<Newly Inserted by Act No. 11251, Feb. 1, 2012>*

1. Broadcasting, daily newspaper, or its equivalents;
2. Medical or pharmaceutical journal or its equivalents;
3. The relevant firm's website or its equivalents.

(4) Matters necessary for a public announcement referred to in paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013>*

Article 73 (Inspection Orders and Test and Inspection Institutions)

(1) The Minister of Food and Drug Safety or a Mayor/Do Governor may order manufacturers of drugs, etc., persons who have obtained marketing approval of drug, or importers to undergo an inspection of drugs, etc., manufactured, imported, or approved or notified for marketing, from a test and inspection institution of drugs, etc. designated by the Minister of Food and Drug Safety pursuant to Article 6 (2) 3 of the Act on Testing and Inspection in the Food and Drug Industry (hereinafter referred to as "test and inspection institution"). *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013>*

(2) Deleted. *<by Act No. 11985, Jul. 30, 2013>*

(3) Deleted. *<by Act No. 11985, Jul. 30, 2013>*

(4) Deleted. *<by Act No. 11985, Jul. 30, 2013>*

Articles 73-2 and 73-3 Deleted. *<by Act No. 11985, Jul. 30, 2013>*

Article 74 (Order for Improvement)

If a facility fails to meet the standards for facilities prescribed in Articles 20 (3), 31 (1) and (4), 34-2 (1), 34-3 (1), 42 (3), and 45 (2) or becomes worn out, squalid or damaged, and consequently the drugs, etc. manufactured by using such facility are likely to fall under any of the subparagraphs of Article 62 (including cases in which such provisions apply mutatis mutandis in Article 66), the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a Si/Gun/Gu may order pharmacy founders, manufacturers of drugs, etc., persons who have obtained marketing approval of drugs, importers, distributors, clinical trial institutions, biological equivalence test institutions and non-clinical trial institutions to improve such facility or not to use the whole or part of such facility until the completion of

improvement. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013; Act No. 13114, Jan. 28, 2015>*

Article 75 (Order to Change Managers, etc.)

If a manager of a manufacturing business of drugs, etc. or a manager of a pharmacy violates this Act or an order issued pursuant to this Act, or if the manager is considered inappropriate as a manager, the Minister of Food and Drug Safety may order the relevant manufacturer to change the manager of the manufacturing business, and the head of a Si/Gun/Gu may order the pharmacy founder to change the manager of the pharmacy. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 76 (Revocation of Permission, Suspension of Business, etc.)

(1) If a manufacturer of drugs, etc.; a person who has obtained marketing approval of a drug; a person who has registered drug substances; an importer; a person who has obtained approval for protocols of clinical trials or biological equivalence tests; a pharmacy founder; or a drug distributor falls under any of the following cases, the Minister of Food and Drug Safety may revoke permission, approval, or registration held by the manufacturer of drugs, etc., person who has obtained marketing approval of a drug, person who has registered drug substances, importer or person who has obtained approval for protocols of clinical trials or biological equivalence tests; close down his/her contract manufacturing business office or factory (limited only to where a report has been filed pursuant to Article 31 (4); hereafter the same shall apply in subparagraph 1 of Article 77); close down his/her business office (limited only to where a report has been filed pursuant to Article 42 (1); hereafter the same shall apply in subparagraph 1 of Article 77); issue an order to prohibit manufacturing or importing products; or issue an order to fully or partially suspend his/her business for a period of up to one year; and the head of a Si/Gun/Gu may impose the same on the pharmacy founder or drug distributor: Provided, That where, in cases falling under subparagraph 4, the relevant business entity is not liable and the purpose of a license or notification is deemed attainable by modifying the components, prescription, etc. of the relevant drugs, etc., only the modification of components, prescription, etc. may be ordered: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10324, May 27, 2010; Act No. 10512, Mar. 30, 2011; Act No. 10788, Jun. 7, 2011; Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013; Act No. 12074, Aug. 13, 2013; Act No. 13114, Jan. 28, 2015; Act No. 13219, Mar. 13, 2015>*

1. Where he/she falls under any of the subparagraphs of Article 5 (limited to an importer in cases falling under subparagraph 5): Provided, That where the representative of a corporation falls under any such provisions and the representative is replaced, such case shall be excluded herefrom;

2. Where he/she falls under any of the subparagraphs of Article 20 (5), or under Article 31 (8) 2 or 42 (4) 2 or 3: Provided, That where the representative of a corporation falls under any of such provisions and the representative is replaced, such case shall be excluded herefrom;

2-2. Where he/she, deceitfully or otherwise fraudulently, files for registration of drug substances under Article 31-2 (1) and (3) (including where such provisions apply mutatis mutandis in Article 42 (5)), files for registration to change any registered matter, or submit reports on such changes;

2-3. Where he/she fails to file for registration to change any registered matter of, or to report changes of, drug substances under Article 31-2 (3) (including where such provision applies mutatis mutandis in Article 42 (5));

3. Where he/she violates this Act or any order issued under this Act;

4. Where he/she manufactures, imports, or markets drugs, etc. which harm or are likely to harm the general public health, or drugs, etc. which are regarded as having no efficacy;

5. Where he/she fails to recall, or take measures necessary to recall, or fails to report, or falsely reports a recall plan pursuant to Article 39 (1);

5-2. Where he/she offers any economic benefit, etc., in violation of Article 47 (2);

5-3. Where he/she markets a drug before the expiration of the registered patent, even though he/she has filed an application for approval or revised approval for marketing such drug after the registered patent expires, in violation of Article 50-4 (1) 2;

5-4. Where he/she markets the drug, the marketing of which has been prevented under Article 50-6 (1) or (2) or 50-9 (1);

5-5. Where he/she violates an order prescribed in Articles 71 (1) and (2) and 72 (1) and (2);

6. Where a pharmacy founder receives a disposition to suspend his/her qualifications as a pharmacist or oriental medicine pharmacist under Article 79 (2).

(2) Where facilities of a person prescribed in paragraph (1) are not in compliance with standards for facilities provided for in Articles 20 (3), 31 (1) and (4), 42 (3) and 45 (2), paragraph (1) shall apply thereto. *<Amended by Act No. 8643, Oct. 17, 2007>*

(3) Among the administrative dispositions under paragraphs (1) and (2), the criteria for administrative dispositions, including the revocation of permission, report, registration, and approval, and the suspension of business against a manufacturer of drugs, etc., a person who has obtained marketing approval of a drug, a person who has filed for registration of drug substances, an importer, and a person who has obtained approval for protocols of clinical trials or biological equivalence tests shall be prescribed by Ordinance of the Prime Minister, and the criteria for administrative dispositions, including the revocation of licenses, registration, and permission, suspension, etc. of qualifications or business of a pharmacist, a oriental medicine pharmacist, a pharmacy founder, or a drug distributor shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 76-2 (Revocation, etc. of Designation)

(1) If a clinical trial institution, biological equivalence test institution or non-clinical trial institution prescribed in Article 34-2 or 34-3 (hereinafter referred to as "inspection institution, etc.") falls under any of the following subparagraphs, the Minister of Food and Drug Safety or the head of a Si/Gun/Gu may revoke the designation of such institution, or may order suspension of business for up to nine months: Provided, That in cases falling under subparagraphs 1, 2 (limited to cases of intention or serious negligence), and 5, he/she shall revoke the designation of such institution: *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013; Act No. 13114, Jan. 28, 2015>*

1. Where designation has been made by fraudulent or other deceptive means;

2. Where the clinical trial results, biological equivalence test results or non-clinical trial results referred to in Article 34-2 (3) or 34-3 (3) have been falsely prepared or issued;

3. Where requirements for designation referred to in Article 34-2 (1) and (4) or 34-3 (1) and (4) have not been satisfied;

4. Where matters to be observed referred to in Article 34-2 (3) or 34-3 (3) have not been observed;

5. Where business has been performed during a business suspension period.

(2) No person whose designation has been revoked pursuant to paragraph (1) shall be re-designated within two years from the date when the designation is revoked.

(3) The criteria for administrative dispositions prescribed in paragraph (1) shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 76-3 (Revocation of Registration of Sellers of Safe and Readily Available Drugs)

(1) The head of a Si/Gun/Gu may revoke the registration of a seller of safe and readily available drugs in any of the following cases: Provided, That he/she shall revoke the registration in cases falling under any of subparagraphs 1 and 3 through 6: *<Amended by Act No. 13655, Dec. 29, 2015>*

1. Where he/she has filed for registration deceitfully or otherwise fraudulently;

2. Where he/she fails to recall, or take measures to recall, drugs, in violation of the former part of Article 39 (1);

3. Where he/she fails to meet the criteria for registration referred to in Article 44-2 (2);

4. Where he/she fails to file for registration to change registered details, in violation of Article 44-2 (3), or has filed for such registration deceitfully or otherwise fraudulently;

5. Where he/she fails to receive education, in violation of Article 44-3 (1);

6. Where he/she fails to observe the matters to be observed by sellers of safe and readily available drugs, in violation of Article 44-4 (applicable only to where such violations are committed at least three times a year);

7. Where he/she fails to abide by matters necessary to establish a distribution system and to maintain order in distribution even after having received the correction order pursuant to Article 69-4, in violation of Article 47 (1);

8. Where he/she sells drugs at a non-designated place, in violation of Article 50 (1);

9. Where he/she fails to comply with the order to submit necessary documents or other data as prescribed in Article 69 (1) 1 or rejects, interferes with, or evades the visit, inspection, inquiry, collection conducted under Article 69 (1) 2 or 3;

10. Where he/she fails to comply with an order of abandonment, etc. issued under Article 71 (1) or an order for recall and abandonment issued under paragraph Article 71 (2), or rejects, interferes with, or evades the measures taken for recall, abandonment, etc. under Article 71 (3);

11. Where he/she fails to comply with the order to make public announcement as prescribed in Article 72 (2).

(2) A person whose registration has been revoked under paragraph (1) shall be prohibited from being re-registered as a seller of safe and readily available drugs within one year from the date on which his/her registration was revoked under paragraph (1).

Article 77 (Hearings)

The Minister of Health and Welfare, the Minister of Food and Drug Safety, a Mayor/Do Governor, or the head of a Si/Gun/Gu who intends to take any of the following dispositions shall hold a hearing: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 10788, Jun. 7, 2011; Act No. 11421, May 14, 2012; Act No. 11690, Mar. 23, 2013; Act No. 13114, Jan. 28, 2015>*

1. Revocation of permission, approval and registration, or closure of a contract manufacturing business office, factory and business office, or issuing orders to ban manufacturing or importing products prescribed in Article 76;

1-2. Revocation of registration prescribed in Article 76-3;

2. Revocation of designation prescribed in Article 76-2 (1);

3. Revocation of a license prescribed in Article 79 (1) or (2).

Article 78 (Pharmaceutical Inspectors)

(1) Pharmaceutical inspectors shall be assigned to the Ministry of Health and Welfare, the Ministry of Food and Drug Safety, Cities/Dos, Sis/Guns/Gus (referring to autonomous Gus of the Special Metropolitan City and Metropolitan Cities) in order to perform the duties of pertinent public officials under Articles 69 (1) and 71 (2). *<Amended by Act No. 11690, Mar. 23, 2013>*

(2) Pharmaceutical inspectors shall be appointed by the Minister of Health and Welfare, the Minister of Food and Drug Safety, Mayors/Do Governors or the heads of Sis/Guns/Gus from among public officials belonging to the Ministry of Health and Welfare, the Ministry of Food and Drug Safety, Cities/Dos or Sis/Guns/Gus. *<Amended by Act No. 11690, Mar. 23, 2013>*

(3) Matters necessary for qualification, appointment, etc. of pharmaceutical inspectors shall be prescribed by Ordinance of the Prime Minister following consultation with the Minister of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

Article 79 (Revocation, etc. of Pharmacist's or Oriental Medicine Pharmacist's Licenses)

(1) If a pharmacist or oriental medicine pharmacist falls under any of subparagraphs 1 through 4 of Article 5, the Minister of Health and Welfare shall revoke his/her license. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) If a pharmacist or oriental medicine pharmacist falls under any of the following cases, the Minister of Health and Welfare may revoke his/her license or order the suspension of qualification as a pharmacist or oriental medicine 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 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 relevant documents or demands drug expenses deceitfully or otherwise fraudulently.

(3) Where a pharmacist or oriental medicine pharmacist falls under any of the following cases, the Minister of Health and Welfare may order the suspension of qualification as a pharmacist or oriental medicine pharmacist by up to one year: *<Amended by 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 oriental medicine pharmacist;
2. Where he/she receives any economic benefit, etc. in violation of Article 47 (3).

(4) Even though a pharmacist's or oriental medicine pharmacist's license is revoked under paragraphs (1) and (2), if a ground for the revocation 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. 9123, Jun. 13, 2008; Act No. 9932, Jan. 18, 2010>*

(5) No disposition of suspension of qualification under paragraph (2) or (3) shall be issued after five years (seven years in cases of the suspension of qualification under paragraph (2) 2) from the occurrence of the ground therefor: Provided, That where a criminal complaint under Article 246 of the Criminal Procedure Act is filed for such ground, the period from the date the criminal complaint is filed to the date the trial of the relevant case is finalized shall not be included in the period of prescription. *<Newly Inserted by Act No. 14328, Dec. 2, 2016>*

Article 79-2 (Pharmaceutical Association and Oriental Pharmacy Association's

Requests, etc. for Disposition of Qualification Suspension)

If a pharmacist or oriental medicine pharmacist violates the criteria for ethics under Article 79 (2) 1, the head of the Pharmaceutical Association or the Oriental Pharmacy Association may request the Minister of Health and Welfare to suspend qualification of such pharmacist or oriental medicine pharmacist, after deliberation and resolution by the Ethics Committee of the Pharmaceutical Association or that of the Oriental Pharmacy Association.

Article 80 (Renewal of Certificates of License, Permission, Registration, etc.)

A person who has obtained a pharmacist's license or a oriental medicine pharmacist's license, a person who has registered opening of a pharmacy, a seller of safe and readily available drugs, or a person who has obtained permission for distribution of drugs shall, as prescribed by Ordinance of the Ministry of Health and Welfare; and a person who has obtained permission for the business of manufacturing drugs, etc. or has reported on the business of contract manufacturing shall, as prescribed by Ordinance of the Prime Minister, renew his/her certificate of license, permit, registration, etc.

Article 81 (Disposition of Penalty Surcharges)

(1) If a manufacturer of drugs, etc., a person who has obtained marketing approval of a drug, an importer, a pharmacy founder, or a drug distributor is subject to a disposition to suspend business prescribed in Article 76, the Minister of Food and Drug Safety, a Mayor/Do Governor or the head of a Si/Gun/Gu may impose a penalty surcharge not exceeding 200 million won (50 million won for a pharmacy founder or

herb druggist) in lieu of such disposition as prescribed by Presidential Decree. In such cases, if a pharmacy founder who has been ordered to suspend qualification as a pharmacist or oriental medicine pharmacist prescribed in Article 79 (2) 2 comes to be subject to a disposition to suspend business under Article 76 (1) 5, the penalty surcharge in lieu thereof shall be imposed not exceeding three times. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>*

(2) The amount of penalty surcharges according to categories, degree, etc. of offenses for which penalty surcharges are imposed pursuant to paragraph (1) and other necessary matters shall be prescribed by Presidential Decree.

(3) When necessary for the collection of penalty surcharges, the Minister of Food and Drug Safety, the 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 submitting documents stating the following matters: *<Amended by Act No. 11690, Mar. 23, 2013>*

1. Taxpayers' personal information;
2. Purpose of use;
3. Data on sales, forming the basis for imposing penalty surcharges.

(4) If a person required to pay a penalty surcharge prescribed in paragraph (1) fails to pay it by the deadline for payment, the Minister of Food and Drug Safety, a Mayor/Do Governor or the head of a Si/Gun/Gu shall revoke the disposition to impose penalty surcharges under paragraph (1), and impose a disposition to suspend business under Article 76 (1) or (2) or collect them in the same manner as national taxes in arrears are collected as prescribed by Presidential Decree, or collect them as prescribed by the Act on the Collection, etc. of Local Non-Tax Revenue: Provided, That where imposing a disposition to suspend business pursuant to Article 76 (1) or (2) is impracticable due to cessation of business, etc. under Article 40, the penalty surcharges shall be collected in the same manner as national taxes in arrears are collected, or be collected as prescribed by the Act on the Collection, etc. of Local Non-Tax Revenue. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 11998, Aug. 6, 2013>*

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

Article 82 (Fees)

(1) Each of the following persons shall pay a fee, as determined by Ordinance of the Ministry of Health and Welfare. The same shall also apply to the modification of matters prescribed by Ordinance of the Ministry of Health and Welfare, such as licenses, registration, and permission:

1. A person who intends to obtain the license of a pharmacist or oriental medicine pharmacist under Article 3 or 4;
2. A person who intends to file for registration for establishment of a pharmacy under Article 20;
3. A person who intends to file for registration as a seller of safe and readily available drugs under Article 44-2;

4. A person who intends to obtain permission for drug distribution business under Article 45;

5. A person who intends to apply for the provision of information on distribution of drugs;

6. A person who intends to apply for the national examination for pharmacists, etc.;

7. A person who requests other matters prescribed by Ordinance of the Ministry of Health and Welfare.

(2) Where a person intends to perform the following activities in connection with the affairs under the jurisdiction of the Ministry of Food and Drug Safety, he/she shall pay a fee as prescribed by Ordinance of the Prime Minister. The same shall also apply to permission, renewal, registration, report, or approval, or the modification of the matters prescribed by Ordinance of the Prime Minister: *<Amended by Act No. 13219, Mar. 13, 2015>*

1. Applying for permission, renewal, registration, report, approval, designation, or a preliminary examination;

2. Determining the norm of new products;

2-2. Filing an application for registration of a drug patent, change of registered matters, marketing prevention or exclusive marketing approval under Article 50-2, 50-3, 50-5 or 50-7;

2-3. Filing an application for the change of the registered matters during the further period referred to in the proviso of Article 50-3 (2);

3. Requesting other matters prescribed by Ordinance of the Prime Minister.

Article 82-2 (Registration Fees)

(1) Each registered patentee shall pay a registration fee calculated, on a yearly basis, from the date of registration of a drug patent, as prescribed by Ordinance of the Prime Minister.

(2) Where a registration fee referred to in paragraph (1) is not paid, the Minister of Food and Drug Safety shall delete the relevant drug patent from the patent list.

(3) Matters necessary for the amount, method of payment, period of payment, etc. of registration fees referred to in paragraph (1) shall be prescribed by Ordinance of the Prime Minister.

Article 83 (Subsidization from National Treasury)

The Minister of Health and Welfare and the Minister of Food and Drug Safety may, as prescribed by Presidential Decree, subsidize research funds for the manufacturers of drugs, etc. who have contributed to exportation, or for 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; Act No. 11690, Mar. 23, 2013>*

Article 83-2 (Training of Professionals)

(1) For the enhancement of national health and the promotion of the pharmaceutical industry, the Minister of Health and Welfare and the Minister of Food and Drug Safety shall endeavor to train professionals.

(2) In order to train professionals prescribed in paragraph (1), the Minister of Health and Welfare and the Minister of Food and Drug Safety may designate institutions or organizations with appropriate personnel, facilities, etc., such as universities, research institutions, etc., as a professional training institution and have them provide necessary education and training, as prescribed by Presidential Decree.

(3) The Minister of Health and Welfare and the Minister of Food and Drug Safety may fully or partially subsidize expenses incurred in relation to training for the professional training institutions designated pursuant to paragraph (2) within budgetary limits, as prescribed by Presidential Decree.

(4) Standards, procedures, etc. for designation of professional training institutions under paragraph (2) shall be prescribed by Presidential Decree.

Article 83-3 (Establishing Stable Supply Base of National Essential Drugs)

(1) The Minister of Health and Welfare and the Minister of Food and Drug Safety shall perform the following affairs regarding national essential drugs:

1. Formulating and implementing comprehensive policies for stable supply of national essential drugs;
2. Supporting the establishment of stable supply base of national essential drugs, research and development thereof, and safe use thereof;
3. Other necessary affairs relevant to stable supply of national essential drugs.

(2) If necessary for national essential drugs, the Minister of Health and Welfare and the Minister of Food and Drug Safety may provide administrative, financial, and technical support.

(3) In order to consult matters necessary for national essential drugs with the head, etc. of the relevant central administration agency, a council for stable supply of national essential drugs shall be established in the Ministry of Food and Drug Safety.

(4) Matters necessary for the organization, operation, etc. of the council for stable supply of national essential drugs under paragraph (3) shall be prescribed by Presidential Decree.

Article 84 (Delegation and Entrustment of Authority)

(1) The Minister of Health and Welfare may partially delegate his/her authority under this Act to the Director of the Korea Centers for Disease Control and Prevention or Mayors/Do Governors, as prescribed by Presidential Decree.

(2) The Minister of Food and Drug Safety may partially delegate his/her authority under this Act to the heads of the regional food and drug administrations, the Director General of the National Institute of Food and Drug Safety Evaluation or Mayors/Do Governors, as prescribed by Presidential Decree.

(3) The Minister of Food and Drug Safety and Mayors/Do Governors may partially delegate their authority under this Act to the heads of Sis/Guns/Gus or the heads of public health clinics, as prescribed by Presidential Decree.

(4) The heads of Sis/Guns/Gus may partially delegate their authority under this Act to the heads of public health clinics, as prescribed by Presidential Decree.

(5) The Minister of Health and Welfare and the Minister of Food and Drug Safety may entrust an organization or the Institute of Drug Safety and Risk Management under Article 67 with some of pharmaceutical affairs under this Act, as prescribed by Presidential Decree.

Article 85 (Exceptions to Drugs, etc. for Animals)

(1) Drugs or quasi-drugs, the purpose of which is to be used exclusively for animals, under the jurisdiction of the Minister of Health and Welfare or the Minister of Food and Drug Safety under this Act, shall be

controlled by the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries, and "Minister of Health and Welfare" or "Minister of Food and Drug Safety" in the corresponding provisions of this Act shall be construed as "Minister of Agriculture, Food and Rural Affairs" or "Minister of Oceans and Fisheries", and "Ordinance of the Ministry of Health and Welfare" or "Ordinance of the Prime Minister" shall be construed as "Ordinance of the Ministry of Agriculture, Food and Rural Affairs" or "Ordinance of the Ministry of Oceans and Fisheries". In such cases, when the Minister of Agriculture, Food and Rural Affairs issues Ordinance of the Ministry of Agriculture, Food and Rural Affairs" or the Minister of Oceans and Fisheries issues Ordinance of the Ministry of Oceans and Fisheries, he/she shall consult with the Minister of Health and Welfare or the Minister of Food and Drug Safety. *<Amended by Act No. 11690, Mar. 23, 2013>*

(2) With respect to drugs for animals used for the treatment or prevention of animal's diseases, and designated as ones that may stay in an animal's body and inflict danger or injury to human health, the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries may determine standards for use of animal drugs, such as animals for which such drugs are used, direction, dosage, and the period banning its use. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013>*

(3) Any person who intends to use animal drugs, the usage standards for which have been determined under paragraph (2), shall observe such standards: Provided, That where he/she uses them in accordance with the treatment or prescription of a veterinarian or a certified marine disease manager, he/she may choose not to observe such standards.

(4) Notwithstanding 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 animal 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 of Agriculture, Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013>*

(5) Notwithstanding Article 44, a person who has established a marine disease management office prescribed by the Aquatic Life Disease Control Act may sell drugs to be used for the treatment of marine life to any person who cultivates such marine life. *<Amended by Act No. 8852, Jul. 21, 2011>*

(6) No person who has obtained permission for a wholesaler of drugs for animals under this Act shall distribute any of the following drugs for animals, which are determined and publicly notified by the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries, without a prescription of a veterinarian or a certified marine disease manager: Provided, That the same shall not apply to where such drugs are distributed among a founder of a veterinary hospital, a founder of a marine disease management office, a pharmacy founder, or a wholesaler of drugs for animals: *<Newly Inserted by Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013>*

1. Drugs for animals which are likely to do harm to human and animal health if misused or abused;

2. Drugs for animals which require expertise of a veterinarian or a certified marine disease manager;

3. Drugs for animals deemed likely to cause disorder in light of their dosage form and pharmacological actions.

(7) A founder of a pharmacy may sell drugs for animals falling under any of the subparagraphs of paragraph (6) without a prescription of a veterinarian or a certified marine disease manager: Provided, That the same shall not apply to any of the following drugs for animals prescribed by the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries: *<Newly Inserted by Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013>*

1. An antibiotic substance preparation for injection;

2. A biological preparation for injection.

(8) Notwithstanding paragraphs (6) and (7), a person who sells drugs for animals pursuant to this Act may sell drugs for animals falling under the subparagraphs of paragraph (6) without a prescription of a veterinarian or a certified marine disease manager, if he/she falls under any of the following cases. In such cases, methods for sale, the management of records and the scope of purchasers, matters to be observed, and other necessary matters shall be prescribed by Ordinance of the Ministry of Agriculture Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries: *<Newly Inserted by Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013>*

1. Where such drugs are sold to a livestock farmer or a fishing household cultivating marine life in an island or a secluded area determined by the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries:

2. Where the use of drugs for animals has been ordered by the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries, a Mayor/Do Governor, or the head of a Si/Gun/Gu for purposes of emergent quarantine pursuant to Article 15 of the Act on the Prevention of Contagious Animal Diseases or Article 13 of the Aquatic Life Disease Control Act.

(9) A person who sells drugs for animals pursuant to this Act shall observe matters prescribed by Ordinance of the Ministry of Agriculture Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries to establish the distribution system and to maintain order in sales of drugs for animals, such as prohibition against an act of collusion, designation of sales places, and management of records. *<Newly Inserted by Act No. 11251, Feb. 1, 2012; Act No. 11690, Mar. 23, 2013>*

(10) A person who manages the affairs of a wholesaler of drugs for animals pursuant to this Act shall undergo an education on safety assurance and quality control of drugs for animals, as prescribed by Ordinance of the Ministry of Agriculture, Food and Rural Affairs or the Ministry of Oceans and Fisheries. *<Newly Inserted by Act No. 13655, Dec. 29, 2015>*

(11) Notwithstanding Article 47 (1), a person who has obtained permission for wholesale of drugs for animals may sell drugs for animals to persons who rear animals or who cultivate fisheries, as prescribed by Ordinance of the Ministry of Agriculture, Food and Rural Affairs or the Ministry of Oceans and

Fisheries. *<Newly Inserted by Act No. 13655, Dec. 29, 2015>*

Article 85-2 (Exceptions to Prophylactic Drugs and Therapeutic Drugs in Cases of National Emergencies, etc.)

(1) In order to properly address the violent spread of bioterror infectious diseases prescribed in the Infectious Disease Control and Prevention Act and other infectious diseases, or address circumstances in a nuclear emergency prescribed in Article 2 (1) 7 of the Act on Measures for the Protection of Nuclear Facilities, etc. and Prevention of Radiation Disasters, the Minister of Food and Drug Safety may perform any of the following acts at the request of the heads of relevant ministries:

1. Notwithstanding Article 31 (2), allowing a drug manufacturer to manufacture a drug not approved or notified for marketing;
2. Notwithstanding Article 42 (1), allowing an importer to import a drug not approved or notified for marketing;
3. Allowing a drug manufacturer to manufacture a drug or an importer to import a drug not approved or notified for marketing, specifying other uses, dosage, efficacy, effect, period of use, etc. inconsistent with the details approved or notified.

(2) Where the Minister of Health and Welfare intends to extend the term of validity of a drug stored pursuant to Article 40 (1) of the Infectious Disease Control and Prevention Act, he/she may request the Minister of Food and Drug Safety to extend the term of validity.

(3) Matters necessary for the types and subjects of drugs for which extension of the term of validity can be requested pursuant to paragraph (2), procedures for requesting the extension of the term of validity, and the condition, methods, standards, etc. of storage may be prescribed by Ordinance of the Prime Minister.

Article 85-3 (Exceptions to Ginseng Varieties under Ginseng Industry Act)

(1) A ginseng varieties inspection agency specified in Article 17 (1) of the Ginseng Industry Act (hereafter referred to as “ginseng varieties inspection agency” in this Article) may file an application for permission for drug manufacturing business pursuant to Article 31 (1), and may file, pursuant to Article 31 (2), an application for marketing approval, or file marketing notification, of the red ginseng and white ginseng inspected by the relevant ginseng varieties inspection agency (referring to red ginseng and white ginseng defined in subparagraphs 3 and 5 of Article 2 of the Ginseng Industry Act, excluding imported ones; hereinafter the same shall apply).

(2) A person who has submitted a report under Article 12 (1) of the Ginseng Industry Act (hereafter referred to as “ginseng varieties manufacturer” in this Article) may sell the red ginseng and white ginseng approved or notified for marketing pursuant to paragraph (1), to any of the following persons, notwithstanding Article 44:

1. Herb druggists;
2. Drug wholesale dealers;
3. Pharmacy founders;

4. Founders of medical institutions handling herb drugs.

(3) Articles 47, 69, 71, 94, 94-2, 95, 96 and 97 shall apply to any ginseng varieties manufacturer who sells red ginseng and white ginseng pursuant to paragraph (2). In such cases, a ginseng varieties manufacturer shall be construed as a “manufacturer of a drug, etc.” and “person who obtained marketing approval of a drug”, and the "factory, warehouse, store or office of a ginseng varieties manufacturer" shall be construed as a “factory, warehouse, store or office where drugs are manufactured, stored or handled.”

Article 86 (Projects for Relief of Harm from Side Effects of Drugs)

(1) The Minister of Food and Drug Safety shall relieve harm resulting from the side effects of drugs and an organization consisting of drug manufacturers, persons who have obtained marketing approval of a drug, or importers shall conduct research projects to facilitate the improvement of safety of drugs and the development of new drugs. *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 12450, Mar. 18, 2014>*

(2) Drug manufacturers, persons who have obtained marketing of drugs, or importers shall bear expenses incurred in relation to projects prescribed in paragraph (1). *<Amended by Act No. 8643, Oct. 17, 2007>*

(3) The Government may subsidize projects referred to in paragraph (1), within budgetary limits.

(4) Matters necessary for projects referred to in paragraph (1) shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11690, Mar. 23, 2013>*

(5) The Minister of Food and Drug Safety may entrust the Institute of Drug Safety and Risk Management with the project to relieve harm resulting from the side effects of drugs. *<Newly Inserted by Act No. 12450, Mar. 18, 2014>*

Article 86-2 (Charges for Relief of Harm Resulting from Side Effects of Drugs)

(1) For the relief of harm prescribed in Article 86 (1), the Minister of Food and Drug Safety shall impose and collect charges for relief of harm resulting from the side effects of drugs (hereinafter referred to as "charges") on and from drug manufacturers, persons who have obtained marketing approval of drugs, or importers. In such cases, the Minister of Food and Drug Safety may entrust the president of the Institute of Drug Safety and Risk Management with such imposition and collection.

(2) Charges shall consist of basic charges imposed in proportion to the output of drugs or amount of imported drugs classified as prescription drugs or over-the-counter drugs under this Act and additional charges imposed on drugs in need of relief of harm resulting from the side effects as judged by the Minister of Food and Drug Safety after deliberation by the Deliberative Committee, which are prescribed by Presidential Decree to the extent not exceeding any of the following amounts:

1. Basic charges: 1/1,000 of the output of drugs or amount of imported drugs during the preceding year;
2. Additional charges: 25/100 of the amount paid for relief of injury from relevant drugs during the preceding year: Provided, That no additional charge shall exceed 1/100 of the output of drugs or amount of imported drugs during the preceding year.

(3) The president of the Institute of Drug Safety and Risk Management entrusted with the imposition and collection of charges pursuant to the latter part of paragraph (1) shall determine the amount to be collected

as basic charges under paragraph (2) 1 with approval from the Minister of Food and Drug Safety based upon expected expenses for relief of harm, earnings from the operation of charges, government subsidies, etc. within five years, as prescribed by Presidential Decree.

(4) The president of the Institute of Drug Safety and Risk Management who is entrusted with the imposition and collection of charges pursuant to the latter part of paragraph (1) shall keep accounting records of charges separately from other accounting records, and organize and operate a financial operations committee, as prescribed by Presidential Decree, for the imposition, collection, and operation of charges.

(5) Where a person obligated to pay a charge fails to make payment by the payment deadline, the Minister of Food and Drug Safety or the president of the Institute of Drug Safety and Risk Management who is entrusted with the imposition and collection of charges pursuant to the latter part of paragraph (1) shall compel him/her to pay the charge after specifying a period of at least 30 days. In such cases, a surcharge corresponding to a period from the day following a deadline for payment until the day before the day payment is made shall be imposed within the scope not exceeding 3/100 of the unpaid charge, and the rate of surcharge shall be prescribed by Presidential Decree.

(6) Where a person compelled to make payment pursuant to paragraph (5) fails to pay a charge and surcharge, they shall be collected in the same manner as national taxes in arrears are collected.

(7) Methods of collecting charges under paragraph (1), deadline for payment, procedures for payment, raising an objection, and matters necessary for the imposition, collection, etc. shall be prescribed by Presidential Decree.

Article 86-3 (Benefits for Relief of Harm from Side Effects of Drugs)

(1) If a person who uses a drug becomes ill, becomes disabled or dies due to side effects of the drug, the president of the Institute of Drug Safety and Risk Management shall pay him/her any of the following benefits for relief of harm (hereinafter referred to as "benefits for relief of harm"):

1. Medical expenses;
2. Lump-sum disability payments;
3. Lump-sum death payments;
4. Funeral expenses.

(2) Where, notwithstanding paragraph (1), any of following subparagraphs is applicable, no benefit for relief of harm shall be paid:

1. Drugs determined by the president of the Institute of Drug Safety and Risk Management, which are used for cancer or specific diseases;
2. Where a disease, disability or death due to a side effect of a drug has been caused by inoculation prescribed in the Infectious Disease Control and Prevention Act;
3. Where a disease, disability or death has been caused by intentionally or by gross negligence of the injured;

4. Where a disease, disability or death has been caused by a medical accident prescribed in the Act on Remedies for Injuries from Medical Malpractice and Mediation of Medical Dispute;

5. Where money and things equivalent to the relief payments have already been paid according to the Civil Act or other Acts and subordinate statutes on the grounds of the same disease, disability or death;

6. Other cases prescribed by Ordinance of the Prime Minister.

(3) Standards for the payment of benefits for relief of harm and scope thereof, other matters necessary for payment, etc. shall be prescribed by Ordinance of the Prime Minister.

Article 86-4 (Procedures for Relief of Harm from Side Effects of Drugs, etc.)

(1) A person who intends to receive benefits for relief of harm shall file an application for payment of benefits for relief of harm with the president of the Institute of Drug Safety and Risk Management together with documents prescribed by Ordinance of the Prime Minister.

(2) The president of the Institute of Drug Safety and Risk Management, in receipt of an application for benefits for relief of harm, shall promptly investigate the details of side effects or harm, verify whether the case corresponds to a medical mishaps, inquire into the causal relationship with drugs, investigate whether aftereffects of disability occur, and conduct inspection, appraisal, etc. of scope of indemnity for injury, restrictions on the payment of benefits for relief of harm, etc.

(3) The president of the Institute of Drug Safety and Risk Management shall file a request for deliberation with the Deliberative Committee, along with findings of an inspection prescribed in paragraph (2) and an opinion on appraisal within 90 days from receipt of a request for benefits for relief of harm: Provided, That where conducting inspection and appraisal is impracticable due to new side effects, etc., the period may be extended by up to 30 days limited to one time only.

(4) Where the Deliberative Committee decides to pay benefits for relief of harm as a result of deliberation, the president of the Institute of Drug Safety and Risk Management shall pay the benefits for relief of harm within 30 days from the date of such decision.

(5) Where payment of benefits for relief of harm is not made as payment is restricted on an applicant pursuant to Article 86-3 (2) as a result of deliberation under paragraph (4), the president of the Institute of Drug Safety and Risk Management shall notify the applicant of the fact and grounds for restriction. In such cases, if the president of the Institute of Drug Safety and Risk Management judges that the applicant is eligible for indemnity pursuant to the Civil Act or other Acts and subordinate statutes, the president may guide him/her as to the method for obtaining such, as prescribed by Ordinance of the Prime Minister.

(6) An application for the payment of benefits for relief of harm shall be filed within the following periods:

1. Article 86-3 (1) 1: Five years from the relevant medical treatment;

2. Article 86-3 (1) 2 through 4: Five years from the date disability or death occurs.

(7) Where the results of deliberation by the Deliberative Committee and the results of deliberation by the Medical Dispute Mediation and Arbitration Committee prescribed in the Act on Remedies for Injuries from Medical Malpractice and Mediation of Medical Dispute. mutually conflict, the Minister of Food and

Drug Safety and the president of the Institute of Drug Safety and Risk Management shall hold consultation for mediation.

(8) Where the president of the Institute of Drug Safety and Risk Management has an objection against the conclusion from deliberation by the Deliberative Committee, he/she may request the Minister of Food and Drug Safety to make a new decision. In such cases, the Minister of Food and Drug Safety shall consult with the Central Pharmaceutical Affairs Council thereabout and notify the president of the Institute of Drug Safety and Risk Management of the results thereof; and the president of the Institute of Drug Safety and Risk Management shall pay benefits for relief of harm within 30 days from the date the Minister of Food and Drug Safety makes a new decision.

(9) Matters necessary for mediation prescribed in paragraphs (2) through (8), procedures and methods therefor, etc. shall be prescribed by Ordinance of the Prime Minister.

Article 86-5 (Determination to Cease Payment of Benefits for Relief of Harm, Collection of Unfair Gains, etc.)

(1) Where an applicant is deemed to have aggravated the disease by intention or gross negligence, or refused or obstructed medical treatment, the president of the Institute of Drug Safety and Risk Management may fully or partially cease to pay the benefits for relief of harm.

(2) Where a person in receipt of benefits for relief of harm falls under any of the following, the president of the Institute of Drug Safety and Risk Management shall recover the benefits for relief of harm (referring to twice the amount of benefits for relief of harm in cases under subparagraph 1) and deposit them in the charges account as earnings:

1. Where he/she has received benefits for relief of harm by deceit or other fraudulent means;
2. Where adjustment or mediation is made or conducted for him/her as the case has been proved to be a medical misadventure after benefits for relief of harm are paid to him/her;
3. Where benefits for relief of harm have been paid erroneously.

(3) Matters necessary for the cessation of payment of benefits for relief of harm, collection thereof, etc. under paragraph (1) and (2) shall be prescribed by Ordinance of the Prime Minister.

Article 86-6 (Inspection of Harm from Side Effects, etc.)

(1) Where the president of the Institute of Drug Safety and Risk Management conducts an inspection and appraisal prescribed in Article 86-4 (2), he/she may request applicants, drug manufacturers, persons who have obtained marketing approval, importers, distributors, pharmacy founders, medical institution founders, persons who sell or handle the relevant drug, interested persons, or expert witnesses to appear and make a statement or to submit information, things, etc. necessary for inspection.

(2) Where the president of the Institute of Drug Safety and Risk Management conducts inspection and appraisal under Article 86-4 (2), he/she may request the medical practitioner (including the relevant medical institution founder) who prescribed the drug causing side effects or the pharmacist who dispensed such drug to make a verbal or written statement on the condition of the patient as at the time of prescription and dispensing and on the prescription and dispensing.

(3) Where the president of the Institute of Drug Safety and Risk Management conducts an inspection and appraisal prescribed in Article 86-4 (2), he/she may have access to a drug manufacturer, person who has obtained marketing approval, importer, distributor, medical institution, pharmacy, etc. that prescribed or dispensed the relevant drug to inspect, peruse or duplicate relevant documents or things. In such cases, the inspector shall carry a certificate indicating his/her authority and show it to interested persons. *<Amended by Act No. 13655, Dec. 29, 2015>*

(4) For the inspection necessary to ascertain the causation of side effects for a person who has filed an application for benefits for relief of harm, the president of the Institute of Drug Safety and Risk Management may request a government agency or an institution prescribed in the Act on the Management of Public Institutions to provide information in a form by which personal information can be identified for data matching. In such cases, a person in receipt of such request shall comply therewith, except in extenuating circumstances.

(5) Except as otherwise provided for in paragraphs (1) through (4), matters necessary for the inspection and appraisal of harm from side effects shall be prescribed by Ordinance of the Prime Minister.

(6) Except as otherwise provided for in this Act, the Framework Act on Administrative Investigations shall apply to the procedure, method, etc. of inspecting, perusing or duplicating documents or things under paragraph (3). *<Newly Inserted by Act No. 13655, Dec. 29, 2015>*

Article 86-7 (Protection of Rights to Benefits for Relief of Harm)

No right to benefits for relief of harm prescribed in this Act shall be transferred, seized, or provided as security.

Article 86-8 (Exemption from Public Dues, etc.)

The State or local governments shall not impose public dues on an amount paid as benefits for relief of harm.

Article 87 (Preventing Leakage of Confidential Information)

(1) Neither pharmacist nor oriental medicine pharmacist shall leak other 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. *<Amended by Act No. 8643, Oct. 17, 2007>*

(2) No person who has become aware of trade secrets of a person who has obtained marketing approval of a drug, an importer, a drug wholesaler, etc. in the course of performing business under Article 47-3 (2) shall leak the trade secrets to third parties or use them for other purposes than the business purposes. *<Newly Inserted by Act No. 8643, Oct. 17, 2007; Act No. 14328, Dec. 2, 2016>*

Article 87-2 (Prohibition against Use of Similar Names)

No person other than a manufacturer of a drug, etc., a person who has filed a report on contract manufacturing business, a person who has obtained marketing approval of a drug, an importer, or a distributer under this Act, shall use similar names prescribed by Ordinance of the Prime Minister, such as pharmaceutical and medicine in his/her trade name.

Article 88 (Protection of Materials Submitted)

(1) With respect to data submitted pursuant to Articles 31, 31-2, 32 through 34, 35-2, or 42, when a person who has submitted such data files a written request for protection of them, the Minister of Food and Drug Safety shall not disclose such data: Provided, That where the Minister of Food and Drug Safety deems it necessary to disclose such data for public interest, he/she may disclose it. *<Amended by Act No. 10788, Jun. 7, 2011; Act No. 11690, Mar. 23, 2013>*

(2) No person who has perused or examined the submitted date, the protection of which is requested under paragraph (1), shall disclose the details of such data that he/she has become aware of.

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

(1) When a manufacturer of a drug, etc., a person who has obtained marketing approval of a drug, a person who has filed a report on contract manufacturing business, a drug distributer (excluding herb druggists), or a person who was designated as an inspection institution, etc. (hereafter referred to as "manufacturer, etc." in this Article and Article 89-2) dies 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.: Provided, That the same shall not apply where such transferee, such corporation surviving the merger or such corporation incorporated by the merger falls under any of the following cases: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10512, Mar. 30, 2011; Act No. 10788, Jun. 7, 2011>*

1. A manufacturer of drugs, etc., a person who has obtained marketing approval of a drug, or a person who has filed a report on contract manufacturing business: Where he/she falls under any of subparagraphs of Article 31 (8);
2. A drug distributor: Where he/she falls under any of subparagraphs of Article 46.

(2) Where a manufacturer of a drug, etc., a person who has obtained marketing approval of a drug, a person who has filed a report on contract manufacturing business, or an importer has transferred his/her business of drugs, etc. for which permission has been obtained or a report has been filed depending on manufactured items or imported items pursuant to Articles 31 (2) through (4) or 42 (1), another manufacturer, person who has obtained marketing approval of a drug, person who has filed a report on contract manufacturing business, or importer who takes over such business shall succeed to the status of the previous manufacturer, person who obtained marketing approval of a drug, person who filed a report on contract manufacturing business, or importer with respect to permission for and report on the relevant items. *<Amended by Act No. 10788, Jun. 7, 2011>*

(3) A person who has succeeded to the status of a manufacturer, etc. pursuant to paragraphs (1) and (2) shall file a report with the Minister of Food and Drug Safety (referring to the head of a Si/Gun/Gu in cases of a drug distributor) within one month from the date of succession, as classified in the following: Provided, That where a successor who succeeded to the status of a manufacturer, etc. pursuant to paragraph (1) falls under any subparagraph of paragraph (1), he/she shall transfer such status to another person within six months from the date when succession commenced: *<Amended by Act No. 11690, Mar. 23,*

2013>

1. A person who has succeeded to the status of a manufacturer of drugs, etc., a person who obtained marketing approval of a drug, or a person who reported on contract manufacturing business: As prescribed by Ordinance of the Prime Minister;

2. A person who has succeeded to the status of a drug distributor: As prescribed by Ordinance of the Ministry of Health and Welfare.

Article 89-2 (Succession to Effects of Dispositions of Administrative Sanctions)

Where the status has been succeeded pursuant to Article 89, effects of the administrative dispositions on the previous manufacturer, etc. and importer shall be succeeded by a transferee, a corporation surviving a merger, or a corporation newly established after a merger for one year from the date on which such disposition took place, and where the procedures for administrative disposition are underway, the procedures for disposition of administrative sanctions may proceed for the transferee, the corporation surviving a merger, the corporation newly established after a merger: Provided, That where a new manufacturer, etc. (excluding the succession of the status by inheritance) and an importer succeed to business, the same shall not apply, unless he/she is aware of such disposition or violation.

Article 90 (Bounty)

A bounty may be paid to any person who has whistle-blown or tipped off the fact of violating the provisions of Article 23, 24 (1) and (2), 26 (1), 27 (1) and (3), or 50 (1) (including cases to which relevant provisions apply mutatis mutandis under Article 44-5 (1)) and (2) to any supervisory agency or any investigative agency as prescribed by Presidential Decree. *<Amended by Act No. 11421, May 14, 2012>*

Article 91 (Establishment of Korea Orphan and Essential Drug Center)

(1) The Korea Orphan and Essential Drug Center (hereinafter referred to as the "Center") shall be established to perform the work of providing information with respect to orphan drugs and national essential drugs and supplying (including the duties of preparation and dosage of drugs; hereinafter the same shall apply) such drugs. *<Amended by Act No. 14328, Dec. 2, 2016>*

(2) The Center shall be a corporation.

(3) The provisions governing a juridical foundation of 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: *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 14328, Dec. 2, 2016>*

1. Collecting information pertaining to orphan drugs and national essential drugs and building a computer network;

2. Supplying orphan drugs and national essential drugs; 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 such project;

3. Projects related to the establishment of stable supply base of, support for research and development of, and support for safe use of national essential drugs;

4. Other projects related to orphan drugs and national essential drugs approved by the Minister of Food and Drug Safety.

(2) Where the Minister of Food and Drug Safety deems it necessary for the Center to implement projects specified in paragraph (1), he/she may provide the Center with financial assistance, etc. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 92-2 (Inspectors to be Deemed Public Officials in Applying Penal Provisions)

A drug epidemiological inspector shall be deemed a public official in applying Articles 129 through 132 of the Criminal Act.

Article 92-3 (Review of Regulation)

The Minister of Food and Drug Safety shall review the appropriateness of exclusive marketing approval and the amount of administrative fines referred to in Article 97-2 on a three-yearly basis (referring to a period before January 1 of the year which becomes every three years) based on January 1, 2015, and take measures, such as improvements.

Article 93 (Penalty Provisions)

(1) Each of the following persons shall be punished by imprisonment with prison labor for not more than five years, or by a fine not exceeding 50 million won: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 13114, Jan. 28, 2015; Act No. 13655, Dec. 29, 2015>*

1. A person who lends his/her license to a third 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 marketing approval of a drug or to file marketing notification, in violation of Article 31 (1) through (4);

5. A person who fails to obtain permission, to submit a report, to obtain permission for modification, or to submit a report on modification, 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 a license pursuant to Article 44 (2) 2;

9. A person who violates Article 53 (1);

10. A person who violates Article 61 (including cases to which relevant provisions apply mutatis mutandis under Article 66);

11. A person who prepares and issues results of clinical trials, biological equivalence tests or non-clinical trials pursuant to Article 34-2 (3) or 34-3 (3) in a false manner.

(2) As for the punishment prescribed in paragraph (1), imprisonment with prison labor and a fine may be imposed concurrently.

Article 94 (Penalty Provisions)

(1) Any of the following persons shall be punished by imprisonment with prison labor for not more than three years, or by a fine not exceeding 30 million won: Provided, That any person who violates Article 87 (1) may be prosecuted only when a criminal complaint is filed against him/her: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 11251, Feb. 1, 2012; Act No. 11421, May 14, 2012; Act No. 13114, Jan. 28, 2015; Act No. 14328, Dec. 2, 2016>*

1. A person who violates Article 3 (3) or 4 (3);
2. A person who engages in collusion, in violation of Article 24 (2);
3. A person who violates the main sentence of Article 34 (1) or Article 34 (3) or (4), or a person who violates an order prescribed in paragraph (6) of the same Article;
3-2. A person who conducts clinical trials or biological equivalence tests without designation, in violation of Article 34-2 (1);
3-3. A person who conducts clinical trials or biological equivalence tests without modified designation, in violation of the main sentence of Article 34-2 (2);
4. A person who violates Article 37 (3) (including where such provision applies mutatis mutandis under Article 42 (5));
5. A person who violates Article 45 (5);
5-2. A person who provides economic benefits, etc. in violation of Article 47 (2) or acquires economic benefits, etc. in violation of paragraph (3) of the same Article. In such cases, any economic benefit, etc. acquired shall be confiscated; or where it is impossible to confiscate such economy benefit, etc., a value equivalent thereto shall be collected;
6. Deleted; *<by Act No. 13655, Dec. 29, 2015>*
7. A person who sells, stores, or displays drugs, in violation of Article 49;
8. A person who violates Article 50 (1) (including cases to which relevant provisions apply mutatis mutandis under Article 44-5 (1));
9. A person who sells, manufactures, imports, stores, or displays drugs, in violation of Article 62 (including cases to which relevant provisions apply mutatis mutandis under Article 66);
9-2. A person who divulges confidential information, in violation of Article 68-9;
10. A person who refuses an order to manufacture a drug or an order to commence work without any just cause, in violation of Article 70 (2);
11. A person who violates an order pursuant to Articles 71 (1) and (2) (including cases to which relevant provisions apply mutatis mutandis under Article 44-5 (1)) and 72 (1) and (2) (including cases to which relevant provisions apply under Article 44-5 (1)), or refuses, obstructs, or evades the recall and abandonment of things, which are conducted by relevant public officials pursuant to Article 71 (3) (including cases to which relevant provisions apply mutatis mutandis under Article 44-5 (1)), and other necessary dispositions;

12. A person who violates Article 87 or 88 (2).

(2) As for the punishment prescribed in paragraph (1), imprisonment with prison labor and a fine may be imposed concurrently.

Article 94-2 Deleted. *<by Act No. 14328, Dec. 2, 2016>*

Article 95 (Penalty Provisions)

(1) Any of the following persons shall be punished by imprisonment with prison labor for not more than one year or by a fine not exceeding ten 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; Act No. 11251, Feb. 1, 2012; Act No. 11421, May 14, 2012; Act No. 11985, Jul. 30, 2013; Act No. 12450, Mar. 18, 2014; Act No. 13114, Jan. 28, 2015; Act No. 13219, Mar. 13, 2015; Act No. 13655, Dec. 29, 2015>*

1. A person who fails to file for registration for incorporation, 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 just cause, 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);

6-2. Deleted; *<by Act No. 13655, Dec. 29, 2015>*

7. A person who fails to perform affairs for safety control, in violation of Article 36 (including cases in which such provision applies mutatis mutandis under Article 42 (5)), 37 (2) (including cases in which such provision applies mutatis mutandis under Article 42 (5)) or 37-3 (1) (including cases in which such provision applies mutatis mutandis under Article 42 (5));
8. A person who violates Article 47 (1) (excluding Article 47 (1) 3 (b) and including cases in which such provision applies mutatis mutandis under Article 44-5 (1)) or (4), or 85 (9);

8-2. A person who removes the seal on a container or package of drugs affixed and sells them, in violation of the main sentence of Article 48;

9. A person who sells prescription drugs, in violation of Article 50 (2);

9-2. A person who is registered under Article 50-2 (4), deceitfully or otherwise fraudulently;

9-3. A person who files an application for marketing prevention or exclusive marketing approval under Article 50-5, deceitfully or otherwise fraudulently;

10. A person who violates Article 60, 64 (1), or 68;

10-2. A person who reports the details of agreement pursuant to Article 69-3, deceitfully or otherwise fraudulently;

11. A person who sells drugs for animals without a prescription, in violation of Article 85 (6) and (7);
12. A person who benefits from the relief of harm by deceit or other fraudulent means prescribed in Article 86-5 (2) 1.

(2) As for the punishment under paragraph (1), imprisonment with prison labor and a fine may be imposed concurrently.

Article 95-2 (Penalty Provisions)

A person who violates Article 26 (2) shall be punished by a fine not exceeding three million won.

Article 96 (Penalty Provisions)

Any of the following persons shall be punished by a fine not exceeding two million won: Provided, That with regard to a person who violates Article 30 (2), the offender may be prosecuted only if a criminal complaint is filed against him/her: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 11251, Feb. 1, 2012; Act No. 11421, May 14, 2012; Act No. 12450, Mar. 18, 2014; Act No. 13114, Jan. 28, 2015; Act No. 13655, Dec. 29, 2015; Act No. 14328, Dec. 2, 2016>*

1. A person who violates Article 24 (3);
2. A person who violates Articles 28, 29, or 30 (1), (2) and (3);
3. A person who violates Articles 37 (1), 37-3 (2), 38 (1), or 47 (1) 3 (b);
3-2. A person who releases any drug onto the market without placing an identification mark thereon or without registering an identification mark, in violation of Article 38-2 (1) (including cases in which such provision applies mutatis mutandis under Article 42 (5));
3-3. A person who releases any drug onto the market without registering a modification, in violation of Article 38-2 (2) (including cases in which such provision applies mutatis mutandis under Article 42 (5));
3-4. A person who fails to prepare an expense report or to retain the relevant expense report, books related thereto, and base data, in violation of Article 47-2 (1);
3-5. A person who prepares an expense report under Article 47-2 (1) in a false manner;
3-6. A person who fails to comply with the request to submit an expense report under Article 47-2 (2), books related thereto, and base data;
4. A person who violates Articles 56 (1), 57, 58, 63 (including cases in which such provision applies mutatis mutandis under Article 66), or 65 (1);
5. A person who refuses, obstructs, or evades inspection, inquiry, collection, etc. by drug epidemiological inspectors or relevant public officials prescribed in Article 68-12 (3) or 69 (1) (including cases in which such provision applies mutatis mutandis in Article 44-5 (1));
6. A person who violates an order to report, to make public announcement, conduct an inspection, engage in repair, make change, etc. prescribed in Articles 69 (1) (including cases in which such provision applies mutatis mutandis under Article 44-5 (1)), 72 (3) and (4), 73, 74, and 75;
7. A person who refuses, obstructs, or evades inspection, perusal, or duplication prescribed in Article 86-6 (3).

Article 97 (Joint Penalty Provisions)

Where the representative of a juristic person, or any agent, employee, or any other person employed by a juristic person or an individual commits an offense described in Article 93, 94, 94-2, 95, 95-2, or 96 in connection with business affairs of the juristic person or the individual, in addition to the punishment of such person, the juristic person or the individual shall be punished by a fine under each relevant Article:

Provided, That where such juristic person or individual has not been negligent in providing due attention and supervision concerning the relevant duties to prevent such offense, this shall not apply.

Article 97-2 (Administrative Fines)

(1) Each person, who fails to report the details of agreement pursuant to Article 69-3 without just cause, shall be punished by an administrative fine not exceeding 50 million won.

(2) The administrative fine referred to in paragraph (1) shall be imposed and collected by the Minister of Food and Drug Safety, as prescribed by Presidential Decree.

Article 98 (Administrative Fines)

(1) Any of the following persons shall be punished by an administrative fine not exceeding one million won: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 11421, May 14, 2012; Act No. 11985, Jul. 30, 2013; Act No. 12450, Mar. 18, 2014; Act No. 13114, Jan. 28, 2015; Act No. 14328, Dec. 2, 2016>*

1. A person who fails to submit the details of a pharmacist or oriental medicine pharmacist, in violation of Article 7;

2. A person who fails to receive training and education prescribed in Article 15;

2-2. A person who uses the word "pharmacy" or similar, in violation of Article 20 (6);

3. A person who fails to observe matters necessary for the management of a pharmacy, in violation of Article 21 (3);

3-2. A person who fails to provide medical counselling, in violation of Article 24 (4);

4. A person who fails to report the discontinuance, etc. of business, in violation of Article 22 or 40;

4-2. A person who fails to receive education, in violation of Article 37-2 (including cases in which such provision applies mutatis mutandis in Article 42 (5));

4-3. A person who fails to receive education, in violation of Article 37-4 (including cases in which such provision applies mutatis mutandis in Article 42 (5));

4-4. A person who fails to report on modification, in violation of the proviso to Article 34 (1) or the proviso to Article 34-2 (2);

4-5. A person who fails to have persons engaged in clinical trials, etc. receive education, in violation of Article 34-4 (1) and (2);

5. A person who fails to report production performance, import performance, etc. of a drug, etc., in violation of Article 38 (2) (including cases in which such provision applies mutatis mutandis in Article 42 (5));

6. Deleted; *<by Act No. 11251, Feb. 1, 2012>*

6-2. A person who fails to report the manufacturing, etc. of pharmacy medication or dispensary medication, in violation of Article 41 (1);

6-3. A person who fails to report on discontinuation, suspension, or resumption of business, in violation of the main sentence of Article 44-2 (4);

6-4. A person who fails to receive education, in violation of an order issued under Article 44-3 (2);

7. A person who fails to abide by any of the matters to be observed by sellers of safe and readily available drugs, in violation of Article 44-4;

7-2. A person who fails to submit any of the details of supply of drugs, in violation of Article 47-2 (2) (including cases to which relevant provisions apply mutatis mutandis under Article 44-5 (2));

7-3. A person who fails to indicate price of a drug on the container or package of a drug, in violation of Article 56 (2) (including cases to which relevant provisions apply mutatis mutandis under Article 44-5 (1)) or 65 (2);

7-4. A person who fails to report on an adverse event, in violation of Article 68-8;

7-5. A person who uses the name “the Institute of Drug Safety and Risk Management” or similar, in violation of Article 68-10;

7-6. A person who fails to appear without just reasons after receiving a request to appear under Article 86-6 (1) (excluding expert witnesses);

7-7. A person who fails to submit data, articles, etc. prescribed in Article 86-6 (1) without just reasons after receiving a request to submit data, articles, etc. (excluding testifiers);

7-8. A person who fails to comply with a request to make a statement prescribed in Article 86-6 (2) without justifiable reasons;

8. Deleted; *<by Act No. 11251, Feb. 1, 2012>*

9. A person who fails to renew a certificate of license, permission, or registration, in violation of Article 80;

10. A person who fails to observe any of the standards for use of animal drugs, in violation of Article 85 (3).

(2) Administrative fines prescribed in paragraph (1) shall be imposed and collected by the Minister of Health and Welfare, the Minister of Food and Drug Safety, 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; Act No. 11690, Mar. 23, 2013>*

(3) through (5) Deleted. *<by Act No. 10788, Jun. 7, 2011>*

Article 98 (Administrative Fines)

(1) Any of the following persons shall be punished by an administrative fine not exceeding one million won: *<Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011; Act No. 11421, May 14, 2012; Act No. 11985, Jul. 30, 2013; Act No. 12450, Mar. 18, 2014; Act No. 13114, Jan. 28, 2015; Act No. 14328, Dec. 2, 2016>*

1. A person who fails to submit the details of a pharmacist or oriental medicine pharmacist, in violation of Article 7;

2. A person who fails to receive training and education prescribed in Article 15;

2-2. A person who uses the word "pharmacy" or similar, in violation of Article 20 (6);

3. A person who fails to observe matters necessary for the management of a pharmacy, in violation of Article 21 (3);

3-2. A person who fails to provide medical counselling, in violation of Article 24 (4);

4. A person who fails to report the discontinuance, etc. of business, in violation of Article 22 or Article 40 (1) (including the cases as applicable mutatis mutandis in Article 42 (5));

4-2. A person who fails to receive education, in violation of Article 37-2 (including cases in which such provision applies mutatis mutandis in Article 42 (5));

4-3. A person who fails to receive education, in violation of Article 37-4 (including cases in which such provision applies mutatis mutandis in Article 42 (5));

4-4. A person who fails to report on modification, in violation of the proviso to Article 34 (1) or the proviso to Article 34-2 (2);

4-5. A person who fails to have persons engaged in clinical trials, etc. receive education, in violation of Article 34-4 (1) and (2);

5. A person who fails to report production performance, import performance, etc. of a drug, etc., in violation of Article 38 (2) (including cases in which such provision applies mutatis mutandis in Article 42 (5));

5-2. A person who fails to take measures necessary for drugs, etc. in violation of Article 40 (2) (including cases in which such provision applies mutatis mutandis in Article 42 (5));

6. Deleted; *<by Act No. 11251, Feb. 1, 2012>*

6-2. A person who fails to report the manufacturing, etc. of pharmacy medication or dispensary medication, in violation of Article 41 (1);

6-3. A person who fails to report on discontinuation, suspension, or resumption of business, in violation of the main sentence of Article 44-2 (4);

6-4. A person who fails to receive education, in violation of an order issued under Article 44-3 (2);

7. A person who fails to abide by any of the matters to be observed by sellers of safe and readily available drugs, in violation of Article 44-4;

7-2. A person who fails to submit any of the details of supply of drugs, in violation of Article 47-3 (2) (including cases to which relevant provisions apply mutatis mutandis under Article 44-5 (2));

7-3. A person who fails to indicate price of a drug on the container or package of a drug, in violation of Article 56 (2) (including cases to which relevant provisions apply mutatis mutandis under Article 44-5 (1)) or 65 (2);

7-4. A person who fails to report on an adverse event, in violation of Article 68-8;

7-5. A person who uses the name “the Institute of Drug Safety and Risk Management” or similar, in violation of Article 68-10;

7-6. A person who fails to appear without just reasons after receiving a request to appear under Article 86-6 (1) (excluding expert witnesses);

7-7. A person who fails to submit data, articles, etc. prescribed in Article 86-6 (1) without just reasons after receiving a request to submit data, articles, etc. (excluding testifiers);

7-8. A person who fails to comply with a request to make a statement prescribed in Article 86-6 (2) without justifiable reasons;

8. Deleted; *<by Act No. 11251, Feb. 1, 2012>*

9. A person who fails to renew a certificate of license, permission, or registration, in violation of Article 80;

10. A person who fails to observe any of the standards for use of animal drugs, in violation of Article 85 (3);

11. A person who uses similar names prescribed by Ordinance of the Prime Minister such as pharmaceutical and medicine, in violation of Article 87-2.

(2) Administrative fines prescribed in paragraph (1) shall be imposed and collected by the Minister of Health and Welfare, the Minister of Food and Drug Safety, 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; Act No. 11690, Mar. 23, 2013>*

(3) through (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: Provided, That the amended provisions of Article 81 shall enter into force on July 4, 2007.

Article 2 (Transitional Measures concerning Enforcement Date)

The previous 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 this Addenda.

Article 3 (Applicability concerning Disposition of Imposition of Penalty Surcharges)

The amended provision of Article 81 (4) shall apply, beginning with a person who receives disposition of penalty surcharges determined on or after July 4, 2007, the enforcement date of the 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 articles 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 articles designated by the Minister of Health and Welfare as stipulated by the Ordinance of the Ministry of Health and Welfare regarding the presentation and sale of drugs in the train, airplane or other places designated by the Minister of Health and Welfare.

Article 5 (Transitional Measures concerning Druggists, etc.)

Druggists (referring to the drug dealers under previous statutes) who have obtained a license pursuant to the previous statutes as of January 13, 1971, the enforcement date of the amended Pharmaceutical Affairs Act (Act No. 2279), and drug sellers shall be subject to the previous statutes.

Article 6 (Transitional Measures concerning Herb Druggists)

Those who have been granted the permission for herb dealers as of January 13, 1971, the enforcement date of the amended Pharmaceutical Affairs Act (Act No. 2279) shall be deemed herb druggists pursuant to this Act.

Article 7 (Transitional Measures concerning Areas Permitted for Herb Dealers)

Those who have left the permitted area due to war or other natural calamities from among the 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 designate the place of residence as a permitted area only if they obtain permission 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 Medical Doctors and Veterinarians)

Where a oriental medical doctor dispenses herbs and herb medications in person which he/she uses for treatment, or a veterinarian dispenses animal drugs in person which he/she uses for treatment, he/she may dispenses them notwithstanding the amended provisions of Article 23 (1) and (2).

Article 9 (Transitional Measures concerning Herb Dispensing by Pharmacists)

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

1. 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 amendment to Pharmaceutical Affairs Act (Act No. 4731) entered into force, who has passed the herbal medicine dispensing examination prescribed by Presidential Decree within 2 years from the date of enforcement of the same Act: Provided, That the herbal medicine dispensing examination shall be taken after obtaining a pharmacist license;

2. Person who was attending a college majoring in pharmacology as at the time the amended Pharmaceutical Affairs Act (Act No. 4731) entered into force, who completed the herb related course stipulated by the Ordinance of the Ministry of Health and Welfare and has succeeded in the herbal medicine dispensing examination prescribed by Presidential Decree within 2 years after the graduation: Provided, That the herbal medicine dispensing examination shall be taken after obtaining a pharmacist license.

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

Druggists in operation as of July 1, 2000, the enforcement date of the amended Pharmaceutical Affairs Act (Act No. 6153) shall not 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 a relevant Si/Gun/Gu branch of the Pharmaceutical Association by a branch, etc. of the Medical Association.

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 as at the time of August 14, 2001, 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 Cases concerning Granting Oriental Medicine Pharmacist License)

Those who have completed 95 credits of herbal medicine related subjects stipulated in Article 3-2 of the amended Enforcement Decree of the Pharmaceutical Affairs Act (No. 14319) as conferred under 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 medicine pharmacists from among those falling under any of the following subparagraphs shall be granted a oriental medicine 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 herb drug department) as of March 6, 1997, who entered the college in 1996 school year or before;

2. Those who have completed a college majoring in pharmacology as of March 6, 1997; or

3. Those who were attending a college other than a college majoring in pharmacology as of March 6, 1997, who entered the college in 1996 or before, and who have finished the 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 oriental pharmacy courses and have obtained a bachelor's degree in pharmacology as at the time the amended Pharmaceutical Affairs Act (Act No. 7635) entered into force shall be deemed those who have obtained a bachelor's degree in oriental pharmacy pursuant to the amended provision of Article 4.

Article 15 (Transitional Measures concerning Qualification for Applying for National Examinations for Pharmacists and Oriental Medicine Pharmacists)

Those who have the qualification for applying for the National Examinations for Pharmacists and oriental medicine pharmacists 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 previous provisions 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 License)

Those who have received the pharmacist's license or oriental medicine pharmacist's license pursuant to the previous provisions at the time when this Act enters into force shall be deemed to have received license pursuant to this Act.

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

Where permission has been obtained from the Minister of Health and Welfare, the Commissioner of the Korea Food and Drug Administration, Mayor/Do Governor, the head of a Si/Gun/Gu, or registration or reporting is

made, or application for permission, registration, etc. is made with a competent agency 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 by administrative agencies or acts towards administrative agencies pursuant to the previous provisions at the time this Act enters into force shall be deemed the acts by administrative agencies or acts towards administrative agencies pursuant to this Act.

Article 20 (Transitional Measures concerning Penalty Provisions and Administrative Fines)

When applying a penalty provision or an administrative fine provision to an act committed before this Act enters into force, the previous provision shall govern.

Article 21 Omitted.

Article 22 (Relationship with Other Statutes)

Where the previous Pharmaceutical Affairs Act or a provision thereof is cited by other statutes as at the time this Act enters into force, this Act or a corresponding provision of this Act shall be deemed to have been cited in place of the previous provision if the corresponding provision exists 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: Provided, That 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, Order, and On-going Activities) Notifications, dispositions, orders, and other acts of administrative agencies or various applications, reports, and other acts to administrative agencies under the previous Pharmaceutical Affairs Act at the time this Act enters into force shall be deemed acts administrative agencies or acts to administrative agencies under this Act corresponding thereto.

(3) (Transitional Measures concerning Penalty Provisions) The offences violated the previous Pharmaceutical Affairs Act at the time this Act enters into force shall be governed by the previous Pharmaceutical Affairs Act in applying penalty provisions or administrative fine provisions.

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 4 Omitted.

Article 5 (Relationship with Other Statutes)

Where the previous Juvenile Reformatory Act or a provision thereof is cited by any other statute as at the time this Act enters into force, this Act or a corresponding provision of this Act shall be deemed cited in place of the previous provision if the corresponding provision exists in this Act.

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.

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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.

ADDENDA <*Act No. 10512, Mar. 30, 2011*>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation: Provided, That the amended provisions of Articles 19, 23 (4), 30 (1), 31 (6), (8) and (11), and 42 (2) shall enter into force on the date of its promulgation.

Article 2 (Applicability to Products, etc. with Drugs, etc. and Medical Devices Combined)

The amended provisions of Article 31 (7) (including cases to which relevant provisions apply mutatis mutandis pursuant to the amended provisions of Article 42 (4)) shall apply, starting with the first application for permission for items or the first report on items filed after this Act enters into force.

Article 3 (Applicability to Submission of Test Results, etc.)

The amended provisions of Article 31 (10) 1 and 2 (including cases to which relevant provisions mutatis mutandis pursuant to the amended provisions of Article 42 (4)) shall apply, starting with the first application for permission for items or the first report on items filed after this Act enters into force.

Article 4 (Transitional Measures concerning Drug Substances Subject to Reporting)

A drug substance, a report on which was filed with the Commissioner of the Korea Food and Drug Administration pursuant to the previous provisions as at the time this Act enters into force, shall be deemed registered pursuant to the amended provisions of Article 31 (2) (including cases which are applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)).

Article 5 (Transitional Measures concerning Drug Wholesalers who Obtained Previous Permission)

A person who has obtained permission for drug wholesalers pursuant to the previous provisions as at the time this Act enters into force shall be deemed obtained permission pursuant to the amended provisions of Article 45: Provided, That he/she shall have facilities prescribed in the amended provisions of Article 45 within two years from the date on which this Act enters into force.

Article 6 Omitted.

ADDENDA <*Act No. 10788, Jun. 7, 2011*>

Article 1 (Enforcement Date)

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

(2) Notwithstanding the provisions of paragraph (1), the amended provisions of subparagraphs 15 through 17 of Article 2, Articles 14 (1), 36 (3), 37, 37-3, 38 (1), 39 (3), 45, 54, 56, 57, 61 (1) 2, 65 (excluding paragraphs (1) 4 and (2)), 68-2 (3), 82, 85 (1), 88 (1), 89, 89-2, 94 (1) 4, 95 (1) (excluding subparagraphs 6-2 and 8), 96, 97, 98 (1) 7-3 and 98 (2) through (5) shall enter into force on the date of its promulgation.

(3) Notwithstanding paragraph (1), the amended provisions of Articles 21 (3) 4, 68-3 through 68-11, 84 (2), 94 (1) 9-2, 98 (1) 7-4 and 7-5 shall enter into force six months after the date of its promulgation: Provided, That Article 2 of this Addenda shall enter into force on the date of its promulgation.

Article 2 (Preparation for Establishment of Institute of Drug Safety and Risk Management)

(1) The Commissioner of the Korea Food and Drug Administration shall appoint no more than 10 establishment members within 30 days from the date on which this Act enters into force to have them take charge of affairs on the establishment of the Institute of Drug Safety and Risk Management and on the appointment of directors and auditors as at the time of its establishment.

(2) The establishment members shall prepare the articles of association of the Institute of Drug Safety and Risk Management and obtain authorization from the Commissioner of the Korea Food and Drug Administration.

(3) The president of the Institute of Drug Safety and Risk Management as at the time of its establishment shall be appointed by the Commissioner of the Korea Food and Drug Administration.

(4) Where the establishment members have obtained authorization under paragraph (2), they shall make an establishment registration of the Institute of Drug Safety and Risk Management without delay and then transfer its affairs to the president of the Institute of Drug Safety and Risk Management.

(5) Where the transfer of affairs referred to in paragraph (4) is completed, the establishment members shall be deemed dismissed.

(6) Expenses, etc. necessary for preparing the establishment of the Institute of Drug Safety and Risk Management shall be covered by the State.

Article 3 (Applicability to Approval, etc. for Clinical Tests, etc.)

The amended provisions of Article 34 (1) shall apply, starting with the first person who applies for approval for a protocol of a clinical trial or biological equivalence test using drugs, etc. after this Act enters into force.

Article 4 (Applicability to Matters to be Stated on Containers, etc.)

The amended provisions of Article 65 (1) 4 shall apply, starting with the quasi-drug first manufactured or imported on or after this Act enters into force.

Article 5 (Applicability concerning Fees)

The amended provisions of Article 82 shall apply, starting with the first application for approval for a protocol on a clinical trial or biological equivalence test and the first designation of a non-clinical trial institution, etc.

Article 6 (Transitional Measures concerning Designation of Clinical Trial Institutions, etc.)

(1) A clinical trial institution designated by the Commissioner of the Korea Food and Drug Administration pursuant to the previous provisions as at the time this Act enters into force shall be deemed a clinical trial institution designated by the Commissioner of the Korea Food and Drug Administration pursuant to the amended provisions of Article 34-2 (1).

(2) A person designated by the Commissioner of the Korea Food and Drug Administration or Mayor/Do Governor pursuant to the previous provisions of Article 73 shall be deemed a quality inspection institution designated by the Commissioner of the Korea Food and Drug Administration or Mayor/Do Governor pursuant to the amended provisions of Article 73 (1).

Article 7 (Transitional Measures concerning Korean Pharmacopoeia)

The Korean Pharmacopoeia publicly notified as at the time this Act enters into force shall be deemed publicly notified as the Pharmacopoeia of the Republic of Korea under the amended provisions of Article 51.

Article 8 (Transitional Measures concerning State-Authorized Drugs)

A drug authorized by the Commissioner of the Korea Food and Drug Administration pursuant to the previous provisions of Article 53 as at the time this Act enters into force shall be deemed a drug, for which lot release was granted by the Commissioner of the Korea Food and Drug Administration pursuant to the amended provisions of Article 53.

Article 9 (Transitional Measures concerning Penalty Provisions)

The acts committed before this Act enters into force shall be governed by the previous provisions in applying penalty provisions or administrative fine provisions.

Article 10 Omitted.

Article 11 (Relationship with Other Statutes)

Where the provisions of the previous Pharmaceutical Affairs Act are cited by other statutes as at the time this Act enters into force, corresponding provisions of this Act shall be deemed cited in lieu of the previous provisions if corresponding provisions exist in this Act.

ADDENDA <*Act No. 10888, Jul. 21, 2011*>

Article 1 (Enforcement Date)

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

Articles 2 through 17 Omitted.

ADDENDUM <*Act No. 11118, Dec. 2, 2011*>

This Act enters into force on the date on which the Free Trade Agreement between the Republic of Korea and the United States of America and Exchange of Letters related to the Free Trade Agreement between the Republic of Korea and the United States of America takes effect: Provided, That the amended provisions of subparagraph 4 of Article 5 shall enter into force on the date of its promulgation, while the amended provisions in the former part of Article 42 (4) of the amended Pharmaceutical Affairs Act (Act No. 10512) shall enter into force on March 31, 2012.

ADDENDA <*Act No. 11141, Dec. 31, 2011*>

Article 1 (Enforcement Date)

This Act shall enter into force on September 1, 2012. (Proviso Omitted.)

Articles 2 through 22 Omitted.

ADDENDA <*Act No. 11251, Feb. 1, 2012*>

Article 1 (Enforcement Date)

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

(2) Notwithstanding the provisions of paragraph (1), the amended provisions of Articles 65-2, 72, 76, 94, 96, and 98 (1) 6 shall enter into force six months after the date of its promulgation.

(3) Notwithstanding the provisions of paragraph (1), the amended provisions of Article 85 and the amended provisions of Article 95 of the partial amendment of the Pharmaceutical Affairs Act (Act No. 10788) shall enter into force 18 months after the date of its promulgation.

Article 2 (Transitional Measures concerning Matters to be Indicated on Containers, or Packages and in Package Inserts of Quasi-Drugs)

Matters which are indicated on containers, packages or package inserts of quasi-drugs (including marks) pursuant to the previous provisions as at the time the amended provisions of Article 65-2 enter into force may be continuously used on containers, packages or package inserts of relevant quasi-drugs, until two years after the date on which the same amended provisions enter into force, notwithstanding the same amended provisions.

Article 3 (Transitional Measures concerning Penalty Provisions and Administrative Fines)

Any acts committed before this Act enters into force shall be governed by the previous provisions in applying penalty provisions or administrative fine provisions.

ADDENDA <*Act No. 11421, May 14, 2012*>

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation: Provided, That the amended provisions of Article 31-5 and the former part of Article 42 (4) shall enter into force on January 1, 2013, and the amended provisions of Article 95 (1) 8 of the amended Pharmaceutical Affairs Act (Act No.

11251) shall enter into force on August 2, 2013.

Article 2 (Special Cases concerning Period of Validity of Marketing Approval or Marketing Notification)

Notwithstanding the amended provisions of Article 31-5 (1) (including cases to which relevant provisions apply mutatis mutandis under the amended provisions of the former part of Article 42 (4)), the period of validity of the drug approved or notified before January 1, 2013 and a drug the re-examination period of which expired before January 1, 2013 shall be extended to the date prescribed and publicly notified by the Minister of Food and Drug Safety within the scope from January 1, 2018 to December 31, 2023. *<Amended by Act No. 11690, Mar. 23, 2013>*

ADDENDA *<Act No. 11690, Mar. 23, 2013>*

Article 1 (Enforcement Date)

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

(2) Omitted.

Articles 2 through 7 Omitted.

ADDENDA *<Act No. 11985, Jul. 30, 2013>*

Article 1 (Enforcement Date)

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

Articles 2 through 5 Omitted.

ADDENDA *<Act No. 11998, Aug. 6, 2013>*

Article 1 (Enforcement Date)

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

Articles 2 and 3 Omitted.

ADDENDA *<Act No. 12074, Aug. 13, 2013>*

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation.

Article 2 (Applicability concerning Suspension of Business)

The amended provisions of Article 76 (1) shall also apply to cases where any administrative disposition is granted with respect to any violation occurred before this Act enters into force.

ADDENDA *<Act No. 12450, Mar. 18, 2014>*

Article 1 (Enforcement Date)

This Act shall enter into force nine months after the date of its promulgation: Provided, That the amended provisions of Articles 5, 20 (6), 45 (2) 2 and 98 (1) 2-2 shall enter into force on the date of

their promulgation; the amended provisions of Articles 2, 24 (4) and 98 (1) 3-2 three months after the date of their promulgation; the amended provisions of Articles 37-4, 42 (4) and 98 (1) 4-3 six months after the date of their promulgation.

Article 2 (Preparation for Imposition, Collection, etc. of Charges)

The Minister of Food and Drug Safety may make preparations necessary for the enforcement of this Act, such as imposition and collection of charges, establishment of an operations organization, etc. from the date this Act is promulgated.

Article 3 (Applicability concerning Relief of Harm)

The relief of harm resulting from the side effects of drugs shall apply, starting with any harm resulting from side effects that occurs for the first time after this Act enters into force.

Article 4 (Phased Application of Extent of Payment of Benefits for Relief of Harm)

The payment of benefits for relief of harm shall begin with a lump-sum death payment within five years, as prescribed by Presidential Decree, but the extent of payment shall be enlarged step by step.

Article 5 (Transitional Measures concerning Incompetent Persons, etc.)

Notwithstanding the amended provisions of Article 5, previous provisions shall apply to persons for whom the effects of pronouncement of incompetence or quasi-incompetence are maintained pursuant to Article 2 of Addenda of the Civil Act as amended by Act No. 10429.

ADDENDA <*Act No. 13114, Jan. 28, 2015*>

Article 1 (Enforcement Date)

This Act shall enter into force eight months after the date of its promulgation: Provided, That the amended provisions of Articles 14, 34-2, 34-3, 37-3, 45 (2) 2, 68-7, 74, 76-2, 93 (1), the main sentence of Article 94 (1) and subparagraphs 3 (limited to the parts related to Article 34 (3) and (4)), 3-2 and 3-3 of the same paragraph, and the main sentence of Article 95 (1) shall enter into force on the date of their promulgation; the amended provisions of Article 33 six months after the date of their promulgation.

Article 2 (Applicability to Approval for Protocols of Clinical Trials, etc.)

The amended provisions of Article 34 (1) shall apply, beginning with the first application for approval for modification of protocols of clinical trials, etc. filed after this Act enters into force.

Article 3 (Applicability to Extension of Term of Validity of Stored Drugs)

The amended provisions of Article 85-2 (2) shall also apply to the drugs stored by the Minister of Health and Welfare as at the time this Act enters into force.

Article 4 (Transitional Measures concerning Identification Marks of Drugs)

(1) The identification mark placed on drugs as determined and publicly notified by the Minister of Food and Drug Safety as at the time this Act enters into force shall be deemed an identification mark placed pursuant to the amended provisions of Article 38-2 (1).

(2) The registration of identification marks placed as publicly notified by the Minister of Food and Drug Safety on drugs determined and publicly notified by the Minister of Food and Drug Safety as at the time

this Act enters into force shall be deemed registration made pursuant to the amended provisions of Article 38-2 (1).

Article 5 (Transitional Measures concerning Reports on Import Business)

A person intending to conduct a business of importing drugs, etc. after this Act enters into force, who is an importer of drugs, etc. and has obtained marketing approval or has filed marketing notification pursuant to previous provisions before this Act enters into force, shall report on import business pursuant to the amended provisions of Article 42 within one year from the enforcement of this Act.

ADDENDA *<Act No. 13219, Mar. 13, 2015>*

Article 1 (Enforcement Date)

This Act shall enter into force on March 15, 2015: Provide, That the amended provision of Article 42 (5) of the partially amended Pharmaceutical Affairs Act No. 13114 shall enter into force on September 29, 2015.

Article 2 (Applicability to Application for Marketing Prevention)

The amended provision of Article 50-5 (1) (including the cases to which the aforesaid provision shall apply mutatis mutandis pursuant to the amended provision of Article 42 (4)) shall begin applying where a person who has filed an application for marketing approval or revised approval of a drug after this Act enters into force is notified pursuant to the amended provision of Article 50-4 (1) or (2) (including the cases to which the aforesaid provision shall apply mutatis mutandis pursuant to the amended provision of Article 42 (4)).

Article 3 (Applicability to Application for Exclusive Marketing Approval)

The amended provision of each subparagraph of Article 50-7 (2) (including the cases to which the aforesaid provision shall apply mutatis mutandis pursuant to the amended provision of Article 42 (4)) shall also apply to the persons who filed a petition for a trial pursuant to the amended provision of each subparagraph of Article 50-7 (2) regarding the registered patent before this Act enters into force (hereafter referred to in this Article as “previous patent trial”). In such cases, the petition for the previous patent trial shall be deemed filed on the date before this Act enters into force.

Article 4 (Applicability concerning Exclusive Marketing Approval)

The amended provision of Article 50-8 (1) 1 (including the cases to which the aforesaid provision shall apply mutatis mutandis pursuant to the amended provision of Article 42 (4)) shall begin applying to the persons who file an application for marketing approval or revised approval of a drug which shall be notified pursuant to the amended provision of Article 50-4 (including the cases to which the aforesaid provision shall apply mutatis mutandis pursuant to the amended provision of Article 42 (4)) after this Act enters into force.

Article 5 (Applicability concerning Marketing Prevention of Same Drugs, Etc.)

The amended provision of Article 50-9 (1) (including the cases to which the aforesaid provision shall apply mutatis mutandis pursuant to the amended provision of Article 42 (4)) shall begin applying to the

drug for which an application for marketing approval is applied or the drug which shall be notified pursuant to Article 50-4 (2) after this Act enters into force.

Article 6 (Applicability concerning Report on Details of Agreement)

The amended provision of Article 69 (3) (including the cases to which the aforesaid provision shall apply mutatis mutandis pursuant to the amended provision of Article 42 (4)) shall begin applying to the cases where agreement is reached pursuant to the amended provision of each subparagraph of Article 69-3 after this Act enters into force.

Article 7 (Applicability concerning Fees)

The amended provision of Article 82 (2) 2-2 shall begin applying to the filing of an application for registration or the change of the registered matters after this Act enters into force.

Article 8 (Applicability concerning Registration Fees)

The amended provision of Article 82-2 shall also apply to the filing of registration before this Act enters into force. In such cases, the enforcement date of this Act shall be deemed the registration date.

Article 9 (Transitional Measures concerning Registration, Etc. of Drug Patents)

(1) Where an application for registration in the drug patent list was filed pursuant to the former provision of Article 31-3 (1) before this Act enters into force, the former provision shall apply to the subject matters and standard of registration, notwithstanding the amended provision of Article 50-2 (4) (including the cases to which the aforesaid provision shall apply mutatis mutandis pursuant to the amended provision of Article 42 (4)).

(2) The drug patent registered in the drug patent list pursuant to the former provision of Article 31-3 (2) before this Act enters into force shall be deemed the drug patent registered in the drug patent list pursuant to the amended provision of Article 50-2 (including the cases to which the aforesaid provision shall apply mutatis mutandis pursuant to the amended provision of Article 42 (4)).

Article 10 (Transitional Measures concerning Change, Etc. of Registered Matters)

The former provision of Article 31-3 (3) shall apply to an application for registration of change where the patent information registered in the patent list was changed before this Act enters into force, notwithstanding the amended provision of Article 50-3 (2) (including the cases to which the aforesaid provision shall apply mutatis mutandis pursuant to the amended provision of Article 42 (4)).

Article 11 (Transitional Measures concerning Change or Deletion of Registered Matters by Authority)

The former provision of Article 31-3 (5) shall apply to the change or deletion by authority of the patent information of a drug registered in the patent list pursuant to the former provision of Article 31-3 (2) before this Act enters into force, notwithstanding the amended provision of Article 50-3 (4) 1 and 3 (including the cases to which the aforesaid provision shall apply mutatis mutandis pursuant to the amended provision of Article 42 (4)).

Article 12 (Transitional Measures concerning Notification of Application of Marketing Approval, Etc.)

The former provision of Article 31-4 shall apply to the person who filed an application for marketing approval of a drug, based on the safety and efficacy information of the listed drug pursuant to Article 31

(2) or (3) before this Act enters into forces, notwithstanding the amended provision of Article 50-4 (1) (including the cases to which the aforesaid provision shall apply mutatis mutandis pursuant to the amended provision of Article 42 (4)): Provided, That where the grounds falling under the amended provision of Article 50-4 (1) 2 through 4 cease to exist after this Act enters into force, the amended provision of paragraph (2) of the same Article shall apply thereto.

Article 13 (Transitional Measures concerning Administrative Dispositions)

The former provision shall apply to the administrative dispositions against the violations before this Act enters into force, notwithstanding the amended provision of Article 76 (1) 5-3.

ADDENDUM *<Act No. 13320, May 18, 2015>*

This Act shall enter into force on October 1, 2015.

ADDENDA *<Act No. 13331, May 18, 2015>*

Article 1 (Enforcement Date)

This Act shall enter into force on the date prescribed by Ordinance of the Prime Minister in consideration of the preparation status of the system necessary to report the handling of narcotics, within a period not exceeding three years from the date of its promulgation: Provided, That ... *<omitted>... the amended provisions of Article 3 of Addenda shall enter into force on the date of its promulgation.*

Articles 2 and 3 Omitted.

ADDENDA *<Act No. 13367, Jun. 22, 2015>*

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. 13425, Jul. 24, 2015>*

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. 13655, Dec. 29, 2015>*

Article 1 (Enforcement Date)

This Act shall enter into force three months after the date of its promulgation: Provided, That the amended provisions of Articles 21 (3), 23-2, 23-3, 26, 27 (4), 30 (3), 44 (1), 45 (8), 52-2, 68-12 (3), 69 (2) and 86-6 (3) shall enter into force one year after the date of its promulgation.

Article 2 (Transitional Measures concerning Penalty Provisions)

Any acts committed before this Act enters into force shall be governed by the former provisions in applying penalty provisions.

ADDENDA *<Act No. 14084, Mar. 22, 2016>*

Article 1 (Enforcement Date)

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

Articles 2 through 4 Omitted.

ADDENDA *<Act No. 14170, May 29, 2016>*

Article 1 (Enforcement Date)

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

Articles 2 and 3 Omitted.

ADDENDA *<Act No. 14328, Dec. 2, 2016>*

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation: Provided, That the amended provisions of Articles 38 (2), 44-5 (2), 47-2 and 47-3, subparagraph 3 of Article 69-4, Articles 83-3 and 87 (2), subparagraphs 3-4 through 3-6 of Article 96 and Article 98 (1) 7-2 shall enter into force six months after the date of its promulgation; and the amended provisions of Article 37-2, 37-4, 40 (1) through (3), 56 (1), 65 (1) and 87-2, 98 (1) 4, 98 (1) 5-2, and 98 (1) 11 shall enter into force one year after the date of its promulgation.

Article 2 (Applicability to Submission, etc. of Expense Report)

The amended provision of Article 47-2 shall begin applying to the next fiscal year of the fiscal year which the enforcement date of the same amended provision belongs to.

Article 3 (Applicability to Change of Labelling of Containers, etc. of Drugs or Quasi-Drugs)

The amended provisions of Articles 56 (1) and 65 (1) shall begin applying to drugs, etc. manufactured or imported after the same amended provision enters into force.

Article 4 (Applicability to Products Manufactured, Processed or Imported Using Similar Names such as Pharmaceutical and Medicine)

The amended provision of Article 87-2 shall begin applying to products manufactured, processed, or imported first after the same amended provision enters into force.

Article 5 (Transitional Measures concerning Change of Labelling of Containers, etc. of Drugs or Quasi-Drugs)

The matters labelled in containers, etc. of drugs, etc. under the former provision at the time this Act enters into force may be used as the labelling of the relevant item until one year after the same amended provision enters into force, notwithstanding the amended provisions of Article 56 (1) and 65 (1).

Article 6 (Transitional Measures concerning Products Manufactured, Processed, or Imported Using Similar Names such as Pharmaceutical and Medicine)

Products manufactured, processed, or imported by using similar names prescribed by Ordinance of the Prime Minister such as pharmaceutical and medicine at the time this Act enters into force may be sold or displayed or transported for sales purposes, or used for business until one year after the same amended provision enters into force, notwithstanding the amended provision of Article 87-2.

Article 7 (Transitional Measures concerning Application of Prescription of Disposition of Suspension)

No disposition of suspension in cases falling under each subparagraph of Article 79 (2) or (3) due to the grounds occurred before this Act enters into force shall be issued after five years (seven years in cases of the suspension of qualification under Article 79 (2) 2) from the occurrence of such grounds before this Act enters into force: Provided, That where a criminal complaint under Article 246 of the Criminal Procedure Act is filed for such ground, the period from the day when the criminal complaint is filed to the date the trial of the relevant case is finalized shall not be included in the period of prescription.

Article 8 (Transitional Measures concerning Penal Provisions)

The former provision shall apply to the application of penal provision against acts before this Act enters into force.

Article 9 (Transitional Measures concerning Administrative Fines)

The former provision shall apply to the application of administrative fines against acts before this Act enters into force.

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