PHARMACEUTICAL AFFAIRS ACT

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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. 13598, Dec. 22, 2015
Act No. 13655, Dec. 29, 2015
Act No. 14084, Mar. 22, 2016

Act No. 14170, May 29, 2016
Act No. 14328, Dec. 2, 2016
Act No. 14560, Feb. 8, 2017
Act No. 14839, Jul. 26, 2017
Act No. 14926, Oct. 24, 2017
Act No. 15534, Mar. 27, 2018
Act No. 15709, jun. 12, 2018
Act No. 15891, Dec. 11, 2018
Act No. 16250, Jan. 15, 2019
Act No. 16556, Aug. 27, 2019
Act No. 17091, Mar. 24, 2020
Act No. 17208, Apr. 7, 2020
Act No. 17472, Aug. 11, 2020
Act No. 17799, Dec. 29, 2020
Act No. 17883, Jan. 5, 2021

CHAPTER I GENERAL PROVISIONS

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 terms used in this Act are defined as follows: *<Amended on Oct. 17, 2007; Feb. 29, 2008; Dec. 29, 2009; Jan. 18, 2010; Jun. 7, 2011; Mar. 23, 2013; Mar. 18, 2014; Dec. 2, 2016; Oct. 24, 2017; Aug. 27, 2019>*

1. The term "pharmaceutical affairs" means the manufacturing, dispensation, evaluation, storage, import, and distribution (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 is responsible for matters concerning pharmaceutical affairs (including those concerning herbal medication), with exception to those concerning herbal drugs; the term "oriental medicine pharmacist" means a person who takes charge of matters concerning pharmaceutical affairs related to herbal drugs and medication thereof; and they respectively 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 (where the founder of a pharmacy engages*

in drug distribution business concurrently, including the place required for the distribution business): 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, treatment, alleviation, care, 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 "herbal drug" means a raw drug collected from animals, plants, or minerals and dried, cut, or refined without altering the original forms in most cases;

6. The term "herbal medication" means any drug made by combining herbal drugs according to the principles 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 treatment, alleviation, care, or prevention of 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) Medication for sterilization, insecticide, and other similar uses for the purpose of preventing infectious diseases;

8. The term "new drug" means a drug composed of new materials, the chemical structure or the construction of substance of which is wholly unique, 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 that meets the standards determined and publicly notified by the Minister of Food and Drug Safety, upon consultations with the Minister of Health and Welfare:

(a) A drug for which the misuse or abuse is of little concern and the safety and effectiveness may be expected even when used without a prescription by a physician or a dentist;

(b) A drug that may be used to treat a disease without the professional knowledge of a physician or a dentist;

(c) A drug that has a relatively small side effect on human bodies in consideration of dosage form and pharmacological action;

10. The term "prescription drug" means a drug that is not an over-the-counter drug;

11. The term "dispensation of a drug" means dispensing drugs for the purposes of treatment, prevention, etc. for a certain disease by a specific individual in accordance with the specific dose regimen through the combination of at least two drugs or by dividing one kind of drug into specified doses according to a

specific prescription;

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

(a) Providing information on the names, dose regimen and dose, efficacy and effects, storage methods, side effects, interactions, properties, etc. of drugs;

(b) Assisting consumers in choosing the necessary drugs without providing diagnostic judgment when distributing 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 and distribution business" means the business of manufacturing and distributing drugs without retaining manufacturing facilities by entrusting a drug manufacturer with the manufacturing and distribution of drugs for which permission for manufacturing and distribution of items is granted by the Minister of Food and Drug Safety;

15. The term "clinical trial" means a trial (including bioequivalence tests) that verifies pharmacodynamic, pharmacokinetic, pharmacological, and clinical effects of drugs, etc. and investigates adverse reactions to the human body to validate the safety and effectiveness of the relevant drugs, etc.: Provided, That clinical research on high-tech regeneration medical services defined under subparagraph 3 of Article 2 of the Act on High-Tech Rehabilitation and Drug Safety and Support, shall be excluded;

16. The term "non-clinical study" means a study conducted through the use of animals, plants, microorganisms, physical or chemical mediums, or the components thereof in the same conditions as those in a laboratory, so as to obtain various data on the nature or safety of study materials which influence the health of humans;

17. The term "bioequivalence test" means a medical examination using a living body to prove bioequivalence, which validates that the bioavailability of two medications containing the same major ingredients is statistically equivalent among clinical trials;

18. The term "orphan drug" means any of the following drugs under subparagraph 4, that is 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, for which an alternative drug does not exist or whose safety or effectiveness has been significantly improved compared to the alternative drug;

19. The term “national essential drug” means a drug essential for health and medical treatment, such as disease control and prevention of a radiation disaster, for which the stable supply is difficult solely due to market functions 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 administrative agency.

CHAPTER II PHARMACISTS AND ORIENTAL MEDICINE PHARMACISTS

SECTION 1 Qualification and Licenses

Article 3 (Qualification and Licenses of Pharmacists)

(1) A person who intends 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 on Feb. 29, 2008; Jan. 18, 2010>*

(2) A pharmacist license prescribed in paragraph (1) shall be granted to any of the following persons: *<Amended on Feb. 29, 2008; Jan. 18, 2010; Feb. 8, 2017; Jan. 15, 2019>*

1. A person who has graduated from a college of pharmacy, received a bachelor's degree in pharmacy, and has passed the national examination for a pharmacist license;
2. A person who has graduated from a foreign college of pharmacy (referring to a college meeting the standards for recognition determined and publicly notified by the Minister of Health and Welfare), obtained a foreign pharmacist license, and has passed a preliminary examination for a pharmacist license and a national examination for a pharmacist license.

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

Article 3 (Qualification and Licenses of Pharmacists)

(1) A person who intends 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 on Feb. 29, 2008; Jan. 18, 2010>*

(2) A pharmacist license prescribed in paragraph (1) shall be granted to any of the following persons: *<Amended on Feb. 29, 2008; Jan. 18, 2010; Feb. 8, 2017; Jan. 15, 2019; Apr. 7, 2020>*

1. A person who has graduated from a college of pharmacy, received a bachelor's degree in pharmacy, and has passed the national examination for a pharmacist license, majoring in pharmacology, accredited by an accredited institution under Article 11-2 of the Higher Education Act;
2. A person who has graduated from a foreign college of pharmacy (referring to a college meeting the standards for recognition determined and publicly notified by the Minister of Health and Welfare), obtained a foreign pharmacist license, and has passed a preliminary examination for a pharmacist license and a national examination for a pharmacist license.

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

(4) Notwithstanding paragraph (2), a person who entered a college majoring in pharmacology, accredited by a recognized institution under Article 11-2 of the Higher Education Act, who graduated from the

college and received the relevant degree shall be deemed a person who has received a bachelor's degree in pharmacy under paragraph (2) 1. *<Newly Inserted on Apr. 7, 2020>*

Article 4 (Qualification and Licenses of Oriental Medicine Pharmacists)

(1) A person who intends 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 on Feb. 29, 2008; Jan. 18, 2010>*

(2) An oriental medicine pharmacist license 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 an oriental medicine pharmacist license.

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

Article 5 (Grounds for Disqualification)

A pharmacist or oriental medicine pharmacist license shall not be granted to any of the following persons: *<Amended on Oct. 17, 2007; Dec. 2, 2011; Feb. 1, 2012; Mar. 18, 2014; Dec. 11, 2018>*

1. A mentally ill person prescribed in subparagraph 1 of Article 3 of the Act on the Improvement of Mental Health and the Support for Welfare Services for Mental Patients: Provided, That this shall not apply to a person who is recognized by a medical specialist as being competent for the responsibility for 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 was sentenced to imprisonment without labor or a heavier punishment declared by a court for 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 institutions or organizations paying the drug expenses by requesting payment of the drug expenses by fraud; hereinafter the same shall apply) and other statutes and regulations related to pharmaceutical affairs and for whom the sentence was not completely executed or the non-execution of such sentence has not become final;
5. A person for whom three years have not elapsed since the revocation of a license for committing crimes under Article 347 of the Criminal Act or for whom two years have not elapsed since the revocation of a license for violating the statutes and regulations related to pharmaceutical affairs.

Article 6 (Issuance and Registration of Licenses)

(1) When the Minister of Health and Welfare issues a pharmacist or oriental medicine pharmacist license, he or she shall register matters relating to the license in the registration register, respectively, and issue the relevant license. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

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

(3) Neither pharmacist nor oriental medicine pharmacist shall lend his or her license obtained pursuant to Article 3 or 4 to any third person. *<Amended on Apr. 7, 2020>*

(4) No person shall be lent a license under Article 3 or 4 and shall arrange the lending of a license. *<Newly Inserted on Apr. 7, 2020>*

(5) Matters necessary for registration of a pharmacist or oriental medicine pharmacist license and issuance thereof shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Apr. 7, 2020>*

Article 7 (Notification by Pharmacists or Oriental Medicine Pharmacists)

(1) A pharmacist or oriental medicine pharmacist shall file a report on actual status of employment, etc. with the Minister of Health and Welfare every three years from the date of obtaining his/her first license, as prescribed by Ordinance of the Ministry of Health, Welfare and Family Affairs. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Jun. 7, 2011; Apr. 7, 2020>*

(2) Where the Minister of Health and Welfare has ordered training and education pursuant to Article 15 (1), he/she may return the report under paragraph (1) to pharmacists or oriental medicine pharmacists who have not completed the relevant training and educational programs. *<Newly Inserted on Apr. 7, 2020>*

(3) The Minister of Health and Welfare may entrust the duty to receive reports referred to in paragraph (1) to a relevant organization, etc., as prescribed by Presidential Decree. *<Newly Inserted on Apr. 7, 2020>*

Article 8 (National Examinations for Pharmacist License and Oriental Medicine Pharmacist License)

(1) National examinations for a pharmacist license, national examinations for an oriental medicine pharmacist license, and preliminary examinations for a pharmacist license (hereinafter referred to as "national examinations, etc.") shall be administered by the Minister of Health and Welfare at least once each year. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Feb. 8, 2017>*

(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, etc. referred to in paragraph (1), as prescribed by Presidential Decree. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Jun. 22, 2015; Feb. 8, 2017>*

(3) The Minister of Health and Welfare may provide subsidies to the Korea Health Personnel Licensing Examination Institute which administer national examinations pursuant to paragraph (2). *<Amended on Feb. 29, 2008; Jan. 18, 2010; Jun. 22, 2015>*

(4) Matters necessary for national examinations, etc. shall be prescribed by Presidential Decree. *<Amended on Feb. 8, 2017>*

Article 9 (Restrictions on Application for Examination)

No person falling under subparagraphs 1 through 3 of Article 5 shall apply for the national examination, etc. *<Amended on Feb. 8, 2017>*

Article 10 (Cheating of Examinees)

(1) A person who cheats on the national examination, etc. shall be suspended from taking the examination, and where the fact of cheating is discovered after a candidate has passed the examination, the pass shall be nullified. *<Amended on Feb. 8, 2017>*

(2) The Minister of Health and Welfare may disqualify persons falling under paragraph (1) from applying for any national examination, etc. for two years. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Feb. 8, 2017>*

SECTION 2 The Pharmaceutical Association and the Oriental Pharmacy Association

Article 11 (The Pharmaceutical Association)

(1) Pharmacists shall establish the Korean Pharmaceutical Association (hereinafter referred to as the "Pharmaceutical Association") to research pharmaceutical affairs, establish a code of ethics, promote the rights and interests of pharmacists, and improve the quality of pharmacists, as prescribed by Presidential Decree.

(2) The Pharmaceutical Association shall be a corporation.

(3) Upon establishment of the Pharmaceutical Association, pharmacists shall automatically become members.

(4) Except as provided in this Act, the provisions of the Civil Act relating to the corporate juridical person shall apply mutatis mutandis to the Pharmaceutical Association.

(5) The Pharmaceutical Association shall establish the Ethics Committee to deliberate and decide on requests for revocation of a license or suspension of qualifications prescribed in Article 79-2. *<Newly Inserted on Jun. 7, 2011; Oct. 24, 2017>*

(6) Matters regarding the organization, operation, etc. of the Ethics Committee shall be prescribed by Presidential Decree. *<Newly Inserted on Jun. 7, 2011>*

Article 12 (The Oriental Pharmacy Association)

(1) Oriental medicine pharmacists shall establish the Association of Korea Oriental Pharmacy (hereinafter referred to as the "Oriental Pharmacy Association") to research pharmaceutical affairs related to herbal drugs and herbal medication, establish a code of ethics, promote the rights and interests of oriental medicine pharmacists, and improve the quality of oriental medicine pharmacists, as prescribed by Presidential Decree.

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

(3) Upon establishment of the Oriental Pharmacy, oriental medicine pharmacists shall automatically become members.

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

(5) The Oriental Pharmacy Association shall establish the Ethics Committee to deliberate and decide on requests for revocation of a license or suspension of qualifications prescribed in Article 79-2. *<Newly Inserted on Jun. 7, 2011; Oct. 24, 2017>*

(6) Matters regarding the organization, operation, etc. of the Ethics Committee shall be prescribed by Presidential Decree. *<Newly Inserted on Jun. 7, 2011>*

Article 13 (Authorization)

(1) In order to establish the Pharmaceutical Association or the Oriental Pharmacy Association, the articles of association and other necessary documents shall be submitted to the Minister of Health and Welfare and authorization from the Minister of Health and Welfare shall be obtained, as prescribed by Presidential Decree. *<Amended on Feb. 29, 2008; 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 the Oriental Pharmacy Association intends to modify its articles of association, it shall obtain authorization therefor from the Minister of Health and Welfare. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

Article 14 (Chapters 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, a Metropolitan City, a Special Self-Governing City, a Do, and a 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 a Special Self-Governing Province; hereinafter the same shall apply) and Guns. *<Amended on Jun. 7, 2011; Jan. 28, 2015>*

(2) When the Pharmaceutical Association or the Oriental Pharmacy Association has established its chapters or branches, it shall, without delay, file a notification thereof with the Special Metropolitan City Mayor, a Metropolitan City Mayor, a Special Self-Governing City Mayor, a Do Governor, or a Special Self-Governing Province Governor (hereinafter referred to as the "Mayor/Do Governor"). *<Amended on 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 qualities. *<Amended on Feb. 29, 2008; 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 on Feb. 29, 2008; Jan. 18, 2010>*

Article 16 (Duties of Cooperation and Entrustment)

(1) Upon receipt of a request for cooperation from the Minister of Health and Welfare concerning projects necessary for the improvement of national public health, pharmaceutical affairs, or the ethics of pharmacists or oriental medicine pharmacists, the Pharmaceutical Association or the Oriental Pharmacy Association shall provide cooperation therein. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

(2) The Minister of Health and Welfare may entrust part of affairs concerning pharmaceutical affairs and the ethics of pharmacists or oriental medicine pharmacists to the Pharmaceutical Association or the Oriental Pharmacy Association, as prescribed by Presidential Decree. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

Article 17 (Subsidization)

Where the Minister of Health and Welfare deems that programs of the Pharmaceutical Association or the Oriental Pharmacy Association are necessary for the improvement of national public health, or orders or entrusts such Association to conduct education, investigation, and research concerning pharmacists or oriental medicine pharmacists, he or she may fully or partially subsidize necessary expenses. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

CHAPTER III PHARMACEUTICAL AFFAIRS ADVISORY COMMITTEE

Article 18 (The Central Pharmaceutical Affairs Advisory Committee)

(1) The Central Pharmaceutical Affairs Advisory Committee (hereafter in this Article, referred to as the "Advisory Committee") shall be established under the authority of the Minister of Food and Drug Safety to respond to inquiries from the Minister of Health and Welfare and the Minister of Food and Drug Safety when requested. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 15, 2019>*

(2) The Advisory Committee shall consist of not more than 100 members, including one Chairperson and two Vice Chairpersons. In such cases, the members who are not public officials shall constitute a majority of the Advisory Committee. *<Newly Inserted on Jan. 15, 2019>*

(3) The Minister of Food and Drug Safety shall serve as the Chairperson of the Advisory Committee, and the Vice Chairpersons shall be appointed from among public officials of the Senior Executive Service of the Ministry of Health and Welfare and the Ministry of Food and Drug Safety, respectively. *<Newly*

Inserted on Jan. 15, 2019>

(4) Members of the Advisory Committee shall be appointed or commissioned by the Minister of Food and Drug Safety, from among the public officials related to pharmaceutical affairs, persons recommended by the head of an organization related to pharmaceutical affairs, or persons with much knowledge and experience in pharmaceutical affairs; and the Minister of Health and Welfare may make a recommendation for a member of the Advisory Committee. <*Newly Inserted on Jan. 15, 2019*>

(5) The term of office of a member shall be two years: Provided, That the term of office of any member who is a public official shall be the period during which he or she retains the relevant position. <*Newly Inserted on Jan. 15, 2019*>

(6) Other matters necessary for the organization, operation, etc. of the Advisory Committee shall be prescribed by Presidential Decree. <*Amended on Jan. 15, 2019*>

Article 19 Deleted. <*Mar. 30, 2011*>

CHAPTER IV PHARMACIES AND DISPENSATION OF DRUGS

SECTION 1 Pharmacies

Article 20 (Registration for Establishment of Pharmacies)

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

(2) A person who intends to establish a pharmacy shall file for registration of establishment with the head of a Si/Gun/Gu (the head of a Gu refers 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 any modification of the registered matters. <*Amended on Feb. 29, 2008; Jan. 18, 2010*>

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

(4) The Mayor/Do Governor may set the standards for registration for establishing a pharmacy by rules of the relevant City/Do, according to the standards prescribed by Presidential Decree.

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

1. Where six months have not elapsed from the date the registration of establishment of a pharmacy has been revoked pursuant to Article 76;
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, flight of stairs, or 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 names unless he or she is registered for establishment of a pharmacy pursuant to paragraph (2). *<Newly Inserted on Mar. 18, 2014>*

Article 21 (Duties to Manage Pharmacies)

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

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

(3) A pharmacist or oriental medicine pharmacist who manages a pharmacy shall observe the following matters necessary for managing such pharmacy: *<Amended on Feb. 29, 2008; Jan. 18, 2010; Jun. 7, 2011; Mar. 23, 2013; Dec. 29, 2015>*

1. He or she shall manage his or her pharmacy and drugs in a manner not to cause any risk to health and hygiene and not to reduce the efficacy of drugs;
2. He or she shall thoroughly oversee his or her employees in order to prevent any incident related to health and hygiene;
3. He or she shall keep any objects likely to cause any risk to health and hygiene off from his or her pharmacy;
4. He or she shall take necessary safety measures, where any side effect, etc. occur in connection with the use of drugs, etc.;
5. Where a pharmacist or oriental medicine pharmacist dispenses or distributes drugs, he or she shall wear an identification tag to ensure that patients can identify his or her status, as prescribed by Ordinance of the Ministry of Health and Welfare (including instructing or supervising university students who engage in dispensation or distribution pursuant to the proviso of Article 23 (1) or 44 (1) to wear an identification tag to ensure that patients can identify his or her status, as prescribed by Ordinance of the Ministry of Health and Welfare);
6. He or 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 cause any risk to public health.

Article 21-2 (Succession to Status of Pharmacy Founders)

(1) Where a pharmacy founder transfers the business operation and the transferee intends to succeed to the status of the former pharmacy founder, the transferee shall file a notification therof with the head of a Si/Gun/Gu within one month from the date of transfer, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) Upon receipt of a notification referred to in paragraph (1), the head of a Si/Gun/Gu shall examine the details of the notification and accept such notification if in compliance with this Act. In such cases, where the transferee is not a pharmacist or oriental medicine pharmacist, or if the transferee falls under any subparagraph of Article 5, the head of a Si/Gun/Gu shall not accept the relevant notification.

(3) Where the notification referred to in paragraph (1) is accepted, the transferee shall succeed to the status of the former pharmacy founder as of the date of transfer.

Article 22 (Notification of Business Closure)

Where a pharmacy founder closes or suspends business of his or her pharmacy or resumes the suspended business, he or she shall file a notification thereof with the head of a Si/Gun/Gu having jurisdiction over his or her pharmacy within seven days from the date of business closure or suspension or business resumption, as prescribed by Ordinance of the Ministry of Health and Welfare: Provided, That the same shall not apply where the period of business suspension is less than one month. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

SECTION 2 Dispensation of Drugs

Article 23 (Dispensation of Drugs)

(1) No person, other than pharmacists or oriental medicine pharmacists, shall dispense drugs, and pharmacists or oriental medicine pharmacists shall dispense drugs within the scope of their licenses: Provided, That university students majoring in pharmacy may dispense drugs to the extent prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

(2) A 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 or she has obtained approval from the head of the relevant Si/Gun/Gu. *<Amended on Dec. 2, 2016>*

(3) A physician or dentist may prescribe prescription drugs and over-the-counter drugs, and a pharmacist shall 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 on Feb. 29, 2008; Dec. 29, 2009; Jan. 18, 2010; Aug. 11, 2020>*

1. Where he or she dispenses drugs in an area where no medical institution exists;
2. Where he or she dispenses drugs for disaster relief because medical institutions become essentially nonexistent in the occurrence of a natural disaster;
3. Cases where the Minister of Health and Welfare or the Commissioner of the Korea Disease Control and Prevention Agency recognizes that an infectious disease occurs or is likely to occur in a group, and sells vaccines against an oral infectious disease;

4. Where he or 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 on Dec. 21, 2007; Feb. 29, 2008; Nov. 2, 2009; Dec. 29, 2009; Jan. 18, 2010; Mar. 30, 2011; Feb. 1, 2012; Jul. 24, 2015; May 29, 2016; Mar. 27, 2018; Jan. 5, 2021>*

1. Where he or she dispenses drugs in an area where no pharmacy exists;

2. Where he or she dispenses drugs for disaster relief because pharmacies become essentially nonexistent in the occurrence of a natural disaster;

3. Where he or she dispenses drugs for an emergency patient or a mentally ill person suffering from schizophrenia, manic-depressive insanity, etc. who is likely to harm oneself or others;

4. Where he or she dispenses drugs for an in-patient; a patient suffering from cholera, typhoid, paratyphoid, shigellosis (bacillary dysentery), enterohemorrhagic escherichia coli, or hepatitis A among patients with infectious diseases referred to in subparagraph 13 of Article 2 of the Infectious Disease Control and Prevention Act; or a person admitted to a social welfare facility under the Social Welfare Services Act (where such person is not a ward of such social welfare facility, limited to dispensation of drugs during the period for which he or she uses such facility);

5. Where he or she administers injections;

6. Where he or she administers drugs, including vaccines to prevent infectious diseases and drugs for medical diagnosis, prescribed by Ordinance of the Ministry of Health and Welfare;

7. Where a physician or dentist serving in a public health center or its branch office under the Regional Public Health Act dispenses drugs for patients, in the performance of his or 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 or she dispenses drugs to veterans with disability ratings of 1 through 3 under the statutes and regulations concerning the honorable treatment and support for persons, etc. of distinguished services to the State; persons with disability ratings of 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 and Establishment of Related Organizations; persons with severe disabilities under the statutes and regulations concerning assistance, etc. to patients from actual or potential aftereffects of defoliants, etc.; persons with disability ratings of 1 and 2 under the statutes and regulations concerning welfare of persons with disabilities and persons with disabilities equivalent thereto; and patients suffering from Parkinson's disease or Hansen's disease;

9. Where he or she dispenses drugs for the treatment of persons having undergone the surgery for transplant of an internal organ and the treatment of patients suffering from AIDS;

10. Where he or she dispenses drugs for soldiers in active service, conscripted policemen, and inmates of correctional facilities 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 admittance facilities under the Act on the Treatment of Protected

Juveniles, Etc., and alien detention facilities under the Immigration Act;

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

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

13. Where he or she is prohibited from disclosing prescriptions for reason of 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 under paragraph (3) 1 or (4) 1 shall be determined by the Minister of Health and Welfare. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

(6) An oriental medicine pharmacist shall dispense herbal drugs according to the prescriptions issued by oriental medical doctors: Provided, That he or she may dispense herbal drugs without prescriptions issued by oriental medical doctors, according to the category of herbal drug prescriptions or a dispensation method determined by the Minister of Health and Welfare. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

(7) A pharmacist engaging in dispensing drugs at a dispensary of a medical institution shall not dispense 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 or she shall check 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 or administered to a patient;

2. Whether the drug contains the ingredients contraindicated for combined use, for specific age groups, during pregnancy, or for other reasons which have been publicly notified 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 check drug information where there is good cause.

(3) Methods and procedures for checking drug information under paragraph (1), good cause for which a pharmacist need not check drug information under 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 entrust the operation of the information system to a specialized institution prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, the Minister of Health and Welfare may support all or part of expenses incurred in operating the information system.

(3) The Minister of Health and Welfare or the head of the specialized institution entrusted under paragraph (2) may request the physicians, dentists, pharmacists, etc. to provide data prescribed by Ordinance of the Ministry of Health and Welfare as information necessary for operation of the information system (including sensitive information under Article 23 of the Personal Information Protection Act and personally identifiable information pursuant to Article 24 of that 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 physicians, dentists, pharmacists, etc. upon receipt of the request shall comply with such request, unless there is a compelling reason not to do so.

(4) The Minister of Health and Welfare may establish and operate a steering committee for the information system for safe use of drugs (hereafter in this Article, referred to as "steering committee") for the smooth 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), entrustment referred to in paragraph (2), organization and operation of the steering 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 good cause.

(2) A pharmacy founder (including persons employed by the relevant pharmacy; hereafter in this Article, the same shall apply) and a medical institution founder (including persons employed by the relevant medical institution; hereafter in this Article, the same shall apply) shall not engage in any of the following collusive conduct: <*Amended on Dec. 11, 2018*>

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 or a medical institution founder offering, requesting, or promising money, valuables, favors, labor, entertainment, and other economic benefits to or from another pharmacy founder or medical institution founder in return for medical prescriptions arranged to favor such founder, either directly or through a third party, or receiving the same from another pharmacy founder or medical institution founder;
3. A medical institution founder directing or inducing any person carrying its medical prescription to obtain 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 pursuant to Article 25 (2) (the same shall apply to any pharmacist who repeatedly dispenses the relevant drugs according to the relevant medical prescription);

5. Other acts 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 or 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 on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

(4) Where a pharmacist dispenses drugs to a patient, he or she shall give the patient or his or her protector necessary oral or written medication counselling in which the directions to take medicines (referring to a written direction or electronic document explaining the details of medication counselling in terminology readily comprehendable by the patient) is written. In such cases, necessary matters, such as the form of medication counselling, shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended on Mar. 18, 2014>*

(5) The Minister of Health and Welfare may take necessary measures for pharmacists to conscientiously offer patients the medication counselling referred to in paragraph (4), by allowing pharmacists to dispense a proper number of medical prescriptions. *<Amended on Mar. 3, 2008; Jan. 18, 2010>*

Article 25 (Preparation of List of Prescription Drugs)

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

(2) A 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 adjusted in the list of prescription drugs of each medical institution under paragraph (1) and a list of prescription drugs of each medical institution which are adjusted from the regional list of prescription drugs.

(3) Upon receipt of the regional list of prescription drugs and the list of prescription drugs of each medical institution from a branch of the Medical Association, etc. under paragraph (2), a branch of the Pharmaceutical Association shall inform pharmacy founders in the relevant area of such lists and require them to secure relevant drugs.

(4) Where a pharmacy founder finds it difficult to secure drugs according to the list of prescription drugs under paragraph (2) and thus it is necessary to adjust the number of items, a branch of the Medical

Association, etc. and a 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 a 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 relevant 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 the name, quantity, dose regimen, dose, etc. of any of drugs stated in a prescription are suspected to fall under any of the following cases, a pharmacist or oriental medicine pharmacist shall not dispense the drug unless he or 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 through an information and communications network under Article 2 (1) 1 of the Act on Promotion of Information and Communications Network Utilization and Information Protection: *<Amended on Jul. 27, 2007; Feb. 29, 2008; Jan. 18, 2010; Dec. 31, 2011; Mar. 23, 2013; Dec. 29, 2015>*

1. Where a drug, for which permission by item or a notification by item is revoked by the Minister of Food and Drug Safety due to any defect in terms of safety and effectiveness of the drug, is prescribed;
2. Where it is impracticable to check a product name or ingredient name of a drug;
3. Where a drug publicly notified by the Minister of Food and Drug Safety as drugs containing ingredients contraindicated for combined use, for specific age groups, or during pregnancy: Provided, That the same shall not apply cases prescribed by Ordinance of the Ministry of Health and Welfare, such as where a physician or dentist states the grounds for prescription by using an information system pursuant to Article 18-2 (1) of the Medical Service Act or states such grounds in a prescription.

(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 on Feb. 29, 2008; Jan. 18, 2010>*

Article 27 (Dispensation of Substitute Drugs)

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

(2) Notwithstanding paragraph (1), a pharmacist may dispense a substitute drug without obtaining prior consent from the physician or dentist who has issued the prescription, in any of the following cases: *<Amended on Mar. 23, 2013>*

1. Where the pharmacist dispenses a substitute drug recognized by the Minister of Food and Drug Safety as having bioequivalence (including drugs that prove their bioequivalence 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 that dispensing a substitute drug is not permissible and has stated in detail the clinical reasons, etc. therefor, such substitute drug shall be excluded herefrom;

2. Where the pharmacist dispenses a substitute drug with the same prescription dose, which has been manufactured by the same drug manufacturer who also manufactures the drug stated in the prescription, and which is different in content but is of the same ingredients and dosage form: Provided, That this shall be limited to 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, among drugs included in the regional list of prescription drugs of the relevant pharmacy; a drug, which is stated in a prescription 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 it is difficult to obtain prior consent of the physician or dentist who has issued the prescription due to any unavoidable reasons.

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

(4) Where a pharmacist dispenses a substitute drug for the drug prescribed in a prescription under paragraph (2), he or she shall inform the physician or dentist who has issued such prescription 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 dispensation: Provided, That the same shall not apply where there exist grounds prescribed by Ordinance of the Ministry of Health and Welfare, such as where the pharmacist dispenses such substitute drug after obtaining prior consent from the physician or dentist who has issued the prescription or where the telephone or fax number stated in the prescription is found to be incorrect. *<Amended on Dec. 29, 2015>*

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

(6) Matters necessary for the methods, procedures, etc. for obtaining consent and informing under paragraphs (1) and (4) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended on Feb. 29, 2008; 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, dose regimen, and dose mentioned in the pertinent prescription and other matters prescribed by Ordinance of the Ministry of Health and Welfare on the containers or packages of drugs dispensed for distribution. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

(2) When a pharmacist or oriental medicine pharmacist has dispensed drugs, he or she shall indicate in the prescription, the date of dispensation and other matters prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

Article 29 (Retainment of Prescriptions)

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

Article 30 (Records of Dispensation)

(1) Where a pharmacist dispenses drugs (including where he or she dispenses drugs without a prescription in accordance with the proviso of Article 23 (3), with the exception of its subparagraphs, and each subparagraph of that Article; hereafter in this Article, the same shall apply) at his or her pharmacy, he or she shall keep records of dispensation (including electronic records) concerning the personal information of a patient, date of dispensation, the names of drugs prescribed, and the days of taking drugs, details of dispensation, details of medication counselling, and other matters prescribed by Ordinance of the Ministry of Health and Welfare and retain such records for five years. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 30, 2011>*

(2) A patient may file a request for perusal of his or her records or issuance of a copy thereof with a pharmacist to verify the details of his or her records. In such cases, the pharmacist upon receipt of such request shall not refuse it without good cause. *<Amended on Dec. 29, 2015>*

(3) No pharmacist shall allow any person other than a patient to verify the details of the patient's records of dispensation, by allowing a perusal of such records or issuing a copy of such records: Provided, That he or 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 on 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 do not exist) of a patient, or a lineal ascendant of the spouse of a patient files a request by attaching the written consent of the patient or a certification, etc. verifying 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 attaching the written consent of the patient or a document evidencing 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 attaching a document evidencing 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 do not exist) of a patient, or a lineal ascendant of the spouse of a patient files a request by attaching a certification, etc. verifying 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 dispensation 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 costs of benefits, verification of entitlement to benefits, follow-up management, evaluation of the reasonableness of health care benefits, adjusted payment of health are benefits, etc.;

6. Where records of dispensation are provided to social security agencies (a Si/Gun/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 benefits, the review, payment, follow-up management, etc. of costs of benefits, or other medical benefit 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 dispensation pursuant to Article 347 of the Civil Procedure Act.

CHAPTER V MANUFACTURING AND IMPORT OF DRUGS

SECTION 1 Manufacturing Business of Drugs

Article 31 (Permission for Manufacturing Business)

(1) A 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 securing the necessary facilities meeting the standards for facilities prescribed by Presidential Decree. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

(2) A manufacturer prescribed in paragraph (1) who intends to distribute drugs manufactured (including cases of entrusting another manufacturer with the manufacture) shall obtain permission for manufacturing and distribution of each item (hereinafter referred to as "permission by item") from the Minister of Food and Drug Safety or file a notification of manufacturing and distribution of each item (hereinafter referred to as "notification by item"), as prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 23,*

2013>

(3) Where a person other than a manufacturer prescribed in paragraph (1) (in cases falling under subparagraph 4, limited to the Korea Orphan and Essential Drug Center referred to in Article 91 (1)) intends to entrust a manufacturer with the manufacturing of any of the following drugs for distribution, he or she shall file a notification of contract manufacturing and distribution business with the Minister of Food and Drug Safety and obtain permission by item, as prescribed by Ordinance of the Prime Minister: *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 28, 2015; Oct. 24, 2017; Dec. 11, 2018>*

1. A drug for which clinical trials (excluding bioequivalence tests; hereafter in this paragraph, the same shall apply) have been conducted after obtaining approval of a clinical trial protocol from the Minister of Food and Drug Safety pursuant to Article 34 (1);
2. A drug 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;
3. A drug prescribed by Ordinance of the Prime Minister, for which manufacturing technology has been transferred to a domestic manufacturer, among the drugs distributed in foreign countries;
4. A drug prescribed in each of the subparagraphs of Article 91 (1), which is handled by the Korea Orphan and Essential Drug Center referred to in that paragraph.

(4) A person who intends to manufacture quasi-drugs for business purposes shall file a notification of manufacturing business with the Minister of Food and Drug Safety after securing the necessary facilities meeting the standards for facilities prescribed by Presidential Decree and shall obtain permission by item or file a notification by item. *<Amended on Mar. 23, 2013>*

(5) A person who has obtained permission by item or filed a notification by item pursuant to paragraph (2) or (3) (hereinafter referred to as "person obtaining permission by item") may establish a business place, as prescribed by Ordinance of the Prime Minister. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

(6) Notwithstanding paragraphs (1) through (4), permission for manufacturing business or permission by item need not be granted or a notification by item need not be filed 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 on Mar. 30, 2011; Mar. 23, 2013>*

(7) Notwithstanding paragraphs (2) through (4), in cases of a product or an item for which a drug, etc. and a medical device are combined or complicatedly created and which has been permitted or notified pursuant to the Medical Devices Act as the preeminent function is that of a medial device, permission by item or a notification by item shall be deemed obtained or filed pursuant to paragraphs (2) through (4). *<Newly Inserted on Mar. 30, 2011>*

(8) None of the following persons shall obtain permission and file a notification of manufacturing business or contract manufacturing and distribution business of drugs, etc.: *<Amended on Mar. 30, 2011; Oct. 24, 2017>*

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

2. A person in whose case one year has not elapsed since the revocation of permission for manufacturing business or the closure of a place of contract manufacturing and distribution business or a factory pursuant to Article 76: Provided, That the foregoing shall not apply to any of the following cases:

(a) A person recognized as capable of performing pharmaceutical affairs by a psychiatrist after being subject to revocation or closure as he or she falls under subparagraph 1 or 3 of Article 5;

(b) A person determined for termination of adult guardianship or limited guardianship by a family court after being subject to revocation or closure as he or she falls under subparagraph 2 of Article 5;

3. A person declared bankrupt and not yet reinstated.

(9) In cases falling under paragraphs (1) through (4), where a person intends to modify any matters prescribed by Ordinance of the Prime Minister among matters permitted or notified, he or she shall obtain permission for modification or file a notification of modification, as prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 30, 2011; Mar. 23, 2013>*

(10) Where an item to be permitted or notified 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 safety and effectiveness 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 on Mar. 30, 2011; Mar. 23, 2013>*

1. Test results and data related thereto;
2. Data on drug substances;
3. Relevant documents;
4. Other necessary data.

(11) Upon receipt of a notification referred to in paragraphs (2) through (4) and (9), the Minister of Food and Drug Safety shall examine the details of notification and accept such notification if in compliance with this Act. *<Newly Inserted on Jan. 15, 2019>*

(12) Where permission for or a notification of manufacturing business or contract manufacturing and distribution business of drugs, etc. or manufacturing and distribution of items is granted or filed under paragraphs (1) through (4) and (9), matters necessary for the subject matters, standards, conditions, management, etc. of permission or notifications shall be prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 30, 2011; Mar. 23, 2013; Jan. 15, 2019>*

Article 31-2 (Registration of Drug Substances)

(1) A person who intends to manufacture and distribute a drug substance of a new drug or a drug substance determined and publicly notified by the Minister of Food and Drug Safety may file for registration of the matters prescribed by Ordinance of the Prime Minister, such as its ingredients, name, and manufacturing method, with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 23, 2013>*

(2) The Minister of Food and Drug Safety shall examine whether the matters registered under paragraph (1) satisfy the standards prescribed by Ordinance of the Prime Minister, inform the relevant applicant of the examination results, and record and keep the details of examination in the drug substance register. In such cases, he or she shall publicly notify the matters prescribed by Ordinance of the Prime Minister, such as the ingredients and manufacturer of the relevant drug substance. *<Amended on Mar. 23, 2013>*

(3) A person who intends to modify important matters prescribed by Ordinance of the Prime Minister among the matters registered pursuant to paragraphs (1) and (2) shall file for registration of modification with the Minister of Food and Drug Safety: Provided, That a person who intends to modify other matters shall report thereon. *<Amended on Mar. 23, 2013>*

(4) In cases of drug substances registered pursuant to paragraphs (1) through (3), permission by item or a notification by item shall be deemed granted or filed under Article 31 (2).

(5) Except as provided in paragraphs (1) through (3), matters necessary for registration of or registration of modification of drug substances, reports of modification thereof, public announcement of registered drug substances, and other matters shall be prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 23, 2013>*

Article 31-3 Deleted. *<Mar. 13, 2015>*

Article 31-4 Deleted. *<Mar. 13, 2015>*

Article 31-5 (Renewal of Permission by Item of Drugs)

(1) The period of validity of permission by item or a notification by item of drugs 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 on 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 permission by item of a drug subject to re-review under Article 32 shall apply after the period of re-review of the relevant drug expires.

(3) Where a person obtaining permission by item intends to distribute the relevant drug continuously after the expiration of the period of validity prescribed in paragraph (1) or (2), he or she shall obtain renewed permission by item from, or file a renewed notification by item with, the Minister of Food and Drug Safety before the period of validity expires. *<Amended on Mar. 23, 2013>*

(4) Where any serious problem is deemed to exist in the safety or effectiveness of drugs, where no data necessary for the renewal under paragraph (3) is submitted, or where other similar cases occur, the Minister of Food and Drug Safety need not renew permission by item or accept a renewed notification by

item, of the relevant drugs. *<Amended on Mar. 23, 2013>*

(5) Where a person obtaining permission by item fails to manufacture a drug during the period of validity prescribed in paragraph (1), permission by item or a notification by item of such drug shall not be renewed in accordance with paragraph (3): Provided, That the same shall not apply to drugs that have not been manufactured due to any unavoidable causes prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 23, 2013>*

(6) Matters necessary for the method of calculating the period of validity under paragraphs (1) and (2) and the standards, methods, procedures, etc. for the renewal of permission by item or a notification by item under paragraphs (3) and (4) shall be prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 23, 2013>*

Article 32 (Re-Review of New Drugs)

(1) Drugs falling under Article 31 (10) for which permission by item is granted under Article 31 (2) and (3)shall undergo a re-review 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 such permission by item has been granted. *<Amended on Oct. 17, 2007; Mar. 30, 2011; Mar. 23, 2013>*

(2) Matters necessary for the methods, procedures, timing, etc. for re-review referred to in paragraph (1) shall be prescribed by Ordinance of the Prime Minister. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

Article 33 (Re-Evaluation of Drugs)

(1) The Minister of Food and Drug Safety may re-evaluate drugs for which the examination of their safety and effectiveness by efficacy or by ingredient or the verification of drug equivalence is deemed necessary, among drugs, etc. for which permission by item or a notification by item has been granted or filed pursuant to Article 31 (2) through (4). *<Amended on Oct. 17, 2007; Mar. 23, 2013; Jan. 28, 2015>*

(2) Matters necessary for the methods, procedures, etc. for re-evaluation referred to in paragraph (1) shall be determined by the Minister of Food and Drug Safety. *<Amended on Mar. 23, 2013>*

Article 34 (Approval for Clinical Trial Protocols)

(1) A person who intends to conduct a clinical trial of drugs, etc. shall prepare a protocol thereof and obtain approval from the Minister of Food and Drug Safety; and even where such person intends to modify any of the approved matters, he or she shall obtain approval of modification, as prescribed by Ordinance of the Prime Minister: Provided, That where such person intends to modify matters prescribed by Ordinance of the Prime Minister from among those in the clinical trial protocol, he or she shall report it to the Minister of Food and Drug Safety. *<Amended on Mar. 23, 2013; Jan. 28, 2015; Oct. 24, 2017>*

(2) Notwithstanding paragraph (1), approval under paragraph (1) need not be granted for clinical trials prescribed by Ordinance of the Prime Minister, such as a trial or test aimed at observing the clinical effects

of distributed drugs, etc. and investigating whether any adverse reaction occurs, on condition that permission by item or a notification by item of such drugs is granted. *<Amended on Mar. 23, 2013; Oct. 24, 2017>*

(3) A person who intends to conduct a clinical trial under paragraph (1) shall observe the following matters: *<Amended on Mar. 23, 2013; Oct. 24, 2017; Dec. 11, 2018>*

1. A clinical trial shall be conducted at an institution conducting clinical trials or an institution conducting the analysis of clinical trial samples designated under Article 34-2 (1): Provided, That the same shall not apply to clinical trials prescribed by Ordinance of the Prime Minister in which participation by a medical institution, other than an institution conducting clinical trials or an institution conducting the analysis of clinical trial samples, is deemed necessary based upon the characteristics of the clinical trials;
2. The person shall comply with the standards for conducting clinical trials, including the use of drugs, etc. manufactured, or imported after being manufactured, in appropriate manufacturing facilities prescribed by Ordinance of the Prime Minister;
3. In the public announcement of the recruitment of subjects for conducting a clinical trial, the person shall inform the name, purpose, and method of the clinical trial; the qualifications and selection standards for test subjects; the names (corporate name), addresses, and contact information of a sponsor and a principal investigator; and foreseeable side effects;
4. Deleted; *<Oct. 24, 2017>*
5. Insurance shall be obtained to indemnify or compensate the subjects of a clinical trial for any damage that may occur to their health; and in cases of paying compensation for the occurrence of damage, the person shall comply with the procedures, etc. for compensation explained to the subjects of a clinical trial in advance pursuant to Article 34-2 (3) 2;
6. The safety information of drugs, etc. for clinical trials shall be evaluated, recorded, retained, and reported, as prescribed by Ordinance of the Prime Minister.

(4) No drugs, etc. manufactured, or imported after being manufactured, for the purpose of clinical trials (excluding bioequivalence tests; hereafter in this paragraph, the same shall apply) shall be used for any purpose other than for clinical trials: Provided, That where approval from the Minister of Food and Drug Safety is obtained, as prescribed by Ordinance of the Prime Minister, as the relevant drugs, etc. fall under any of the following cases, they may be used for any purpose other than for clinical trials; and in such cases, Article 34-2 (3) 2 shall apply mutatis mutandis: *<Amended on Mar. 23, 2013; Oct. 24, 2017>*

1. Where the relevant drugs, etc. are intended to treat a patient with a serious life-threatening disease, such as terminal cancer or AIDS;
2. Where the relevant drugs, etc. are intended to treat 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;

3. Where the relevant drugs, etc. are intended to be used for the purpose of research or analysis (referring to research or analysis conducted without humans as a trial subject).

(5) Where a clinical trial of pharmaceutical medications, blood pharmaceutical medications, gene remedial agents, cell remedial agents, etc., containing questionable ingredients in light of safety or effectiveness, causes or is likely to cause any risk to the public interest or health and hygiene, the Minister of Food and Drug Safety may provide limitations on such clinical trial which is subject to approval under paragraph (1). *<Amended on Mar. 23, 2013; Oct. 24, 2017>*

(6) Where any clinical trial approved under the former and latter parts of paragraph (1) is conducted in violation of the approved matters or raises serious safety and ethical issues, the Minister of Food and Drug Safety may issue an order to halt the clinical trial, to stop use of drugs, etc. for the clinical trial, to recall or destroy such drugs, etc., or to take other necessary measures. *<Amended on Mar. 23, 2013; Oct. 24, 2017>*

(7) Matters necessary for approval of clinical trial protocols referred to in paragraph (1), matters to be included in the protocols, the standards for conducting clinical trials referred to in paragraph (3) 2, and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 23, 2013; Oct. 24, 2017>*

Article 34-2 (Designation of Institution Conducting Clinical Trials)

(1) Any of the following institutions shall obtain designation from the Minister of Food and Drug Safety after securing facilities, professional personnel, and organization prescribed by Ordinance of the Prime Minister according to the following classifications, as prescribed by Ordinance of the Prime Minister: *<Amended on Jan. 28, 2015; Oct. 24, 2017>*

1. An institution intending to conduct clinical trials *[excluding analysis of samples collected or extracted from a human body (hereinafter referred to as "sample analysis")] (limited to a medical institution prescribed in Article 3 of the Medical Service Act);*

2. An institution intending to conduct sample analysis among clinical trials.

(2) Where an institution conducting clinical trials after obtaining designation pursuant to paragraph (1) 1 (hereinafter referred to as "institution conducting clinical trials") or an institution conducting sample analysis after obtaining designation pursuant to subparagraph 2 of that paragraph (hereinafter referred to as "institution conducting the analysis of clinical trial samples") intends to modify any designated matter, it shall obtain designation of modification from the Minister of Food and Drug Safety, 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 file a report to the Minister of Food and Drug Safety. *<Amended on Jan. 28, 2015; Oct. 24, 2017>*

(3) An institution conducting clinical trials or an institution conducting the analysis of clinical trial samples shall comply with the following matters: Provided, That subparagraphs 1 through 4 shall apply only to institutions conducting clinical trials: *<Amended on Oct. 24, 2017; Jun. 12, 2018; Dec. 11, 2018>*

1. Persons under the custody of any group care facilities prescribed by Ordinance of the Prime Minister, such as social welfare facilities, (hereafter in this subparagraph referred to as "inmate") shall not be selected as the subject of a clinical trial: Provided, That an inmate may be selected as the subject of a clinical trial, where the standards prescribed by Ordinance of the Prime Minister are satisfied and where it is inevitable to select an inmate as the subject of a clinical trial in consideration of the characteristics of the clinical trial;

2. An explanation shall be provided in advance to subjects of a clinical trial regarding clinical trial details, the extent of damage that is expected to occur to the health of the subjects due to the clinical trials, the details of compensation therefor, the procedures for applying for the compensation, and other relevant matters; and a written consent thereto (including electronic documents containing digital signatures prescribed in the Digital Signature Act; hereafter in this Article, the same shall apply) shall be obtained from the subjects;

3. Notwithstanding subparagraph 2, where consent of a subject of a clinical trial cannot be obtained due to the lack of comprehension and communication or due to other reasons, a written consent shall be obtained from his or her representative prescribed in the following items. In such cases, the consent of a representative shall not be contrary to the intent of the subject of a clinical trial:

(a) A legal representative;

(b) Where no legal representative is appointed, the spouse, a lineal ascendant, or a linear descendant shall act as a representative for such person in the abovementioned order; and where there exist at least two lineal ascendants or descendants, the representative for such person shall be appointed under agreement by and between such ascendants or descendants, or the eldest person among them shall act as the representative if they fail to reach an agreement;

4. Where any clinical trial is to be conducted on healthy persons, those who have not participated in any clinical trial within six months from the date of the clinical trial shall be selected as the subjects of the clinical trial, as prescribed by Ordinance of the Prime Minister;

5. Upon conducting a clinical trial, the relevant institution shall comply with the matters prescribed by Ordinance of the Prime Minister, such as preparing and issuing a clinical trial report or an analysis report of clinical trial samples, and preparing, keeping, and reporting records on the subjects of the clinical trial (including personally identifiable information referred to in Article 24 of the Personal Information Protection Act); records on adverse reactions that have occurred during the clinical trial; records on the management of drugs used in the clinical trial; and the contract for the clinical trial (hereinafter referred to as "records on a clinical trial").

(4) The Minister of Food and Drug Safety and an institution conducting clinical trials may handle information on health prescribed in Article 23 of the Personal Information Protection Act and data containing personally identifiable information prescribed in Article 24 of that Act after obtaining consent from the relevant persons, to perform the affairs regarding the selection, management, etc. of subjects of clinical trials. In such cases, the Minister of Food and Drug Safety and the institution conducting clinical

trials shall protect the relevant information in accordance with the Personal Information Protection Act *<Newly Inserted on Dec. 11, 2018>*

(5) Except as provided in paragraphs (1) through (4), matters necessary for the requirements, procedures, and methods for designating institutions conducting clinical trials or institutions conducting the analysis of clinical trial samples, and the operation, management, etc. thereof shall be prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 23, 2013; Oct. 24, 2017; Dec. 11, 2018>*

Article 34-3 (Designation of Institutions Conducting Non-Clinical Studies)

(1) An institution that intends to conduct non-clinical studies determined and publicly notified by the Minister of Food and Drug Safety on non-human subjects with regard to the safety and effectiveness of drugs, etc. shall have facilities, professional personnel, and organizations and obtain designation from the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. *<Amended on Jan. 28, 2015>*

(2) Where an institution that conducts non-clinical studies after obtaining designation under paragraph (1) (hereinafter referred to as "institution conducting non-clinical studies") intends to modify any designated matter, it shall obtain designation of modification from the Minister of Food and Drug Safety, 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 file a report to the Minister of Food and Drug Safety. *<Amended on Jan. 28, 2015>*

(3) When an institution conducting non-clinical studies has conducted a non-clinical study under paragraph (1), it shall comply with the matters prescribed by Ordinance of the Prime Minister, such as preparing and issuing non-clinical study reports and retaining records on such non-clinical study. *<Amended on Mar. 23, 2013>*

(4) Except as provided in paragraphs (1) through (3), matters necessary for the requirements, procedures, and methods for designating institutions conducting non-clinical studies and the operation, management, etc. thereof shall be prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 23, 2013>*

Article 34-4 (Education for Persons Engaged in Clinical Trials)

(1) The head of an institution conducting clinical trials and a person intending to conduct a clinical trial pursuant to Article 34 (1) shall have the following personnel (hereinafter referred to as "persons engaged in clinical trials") receive education to enhance expertise and protect subjects of clinical trials (hereinafter referred to as "education on clinical trials"): *<Amended on Oct. 24, 2017>*

1. Persons responsible for conducting clinical trials in an institution conducting clinical trials;
2. Persons monitoring the supervision, verification, and examination of clinical trials;
3. Persons in charge of conducting clinical trials under the delegation and supervision of the persons responsible under subparagraph 1 in an institution conducting clinical trials;

4. Persons prescribed by Ordinance of the Prime Minister, who conduct the affairs of protecting the rights and ensuring safety of the subjects of clinical trials participating in the clinical trials.

(2) The Minister of Food and Drug Safety may order the heads of institutions conducting clinical trials and persons intending to conduct clinical trials to have persons engaged in clinical trials, who are employed thereby, receive education on clinical trials. *<Amended on Oct. 24, 2017>*

(3) The Minister of Food and Drug Safety may designate specialized organizations, institutions, etc. related to clinical trials as an institution to offer education on clinical trials (hereinafter referred to as "institution offering education on clinical trials"). In such cases, the Minister of Food and Drug Safety shall publicly notify the details of designation. *<Amended on Oct. 24, 2017>*

(4) An institution offering education on clinical trials shall observe matters prescribed by Ordinance of the Prime Minister, such as preparing and retaining records on education on clinical trials. *<Amended on Oct. 24, 2017>*

(5) Except as provided in paragraphs (1) through (4), matters necessary for education on clinical trials, such as the details, hours, and methods of education, and education fees, and matters necessary for requirements and procedures for designation of institutions offering education on clinical trials, operation thereof, revocation of designation, etc. shall be prescribed by Ordinance of the Prime Minister. *<Amended on Oct. 24, 2017>*

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 drug manufacturing business 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 on Oct. 17, 2007; Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

(2) If a person who has obtained permission under paragraph (1) fails to be equipped with proper facilities without good cause within the period referred to in paragraph (1), the Minister of Food and Drug Safety shall revoke such permission. *<Amended on Mar. 23, 2013>*

Article 35-2 (Preliminary Examination of Permission by Item of Drugs)

(1) A person who intends to obtain permission by item or file a notification by item of drugs, etc. pursuant to Article 31 and a person who intends to conduct a clinical trial pursuant to Article 34 may request, in advance, the Minister of Food and Drug Safety to examine standards for preparing data necessary for permission, notifications, approval, etc. *<Amended on Mar. 23, 2013; Oct. 24, 2017>*

(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 the examination results in writing (including electronic documents). *<Amended on Mar. 23, 2013; Apr. 7, 2020>*

(3) In granting or filing permission, notifications, 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 on Mar. 23, 2013>*

(4) Matters necessary for the subject matters and scope of preliminary examination under paragraph (1), procedures and methods therefor, etc. shall be prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 23, 2013>*

Article 36 (Manufacturing Managers of Drugs)

(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 or her factories and have them the manage manufacturing affairs, as prescribed by Ordinance of the Prime Minister: Provided, That in cases of business of manufacturing biological medications, 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 technician with bacteriological knowledge prescribed by Ordinance of the Prime Minister manage the manufacturing affairs. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 28, 2015; Aug. 27, 2019>*

(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 or her factories and have them manage the manufacturing affairs: Provided, That where the manufacturer is a technician approved by the Minister of Food and Drug Safety and manages the manufacturing affairs at his or her factories, he or she need not assign an additional technician to such factories. *<Amended on Mar. 23, 2013>*

(3) Where a manufacturer of drugs, etc. intends to have a person who manages the manufacturing affairs of drugs, etc. (hereinafter referred to as "manufacturing manager") pursuant to paragraph (1) or (2), he or she shall file a notification with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. *<Newly Inserted on Jun. 7, 2011; Mar. 23, 2013>*

(4) Upon receipt of a notification referred to in paragraph (3), the Minister of Food and Drug Safety shall examine the details of the notification and accept such notification if in compliance with this Act. *<Newly Inserted on Jan. 15, 2019>*

Article 37 (Duty to Manage Manufacturing of Drugs)

(1) A manufacturing manager 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 management, management of manufacturing facilities, and other matters concerning manufacturing management. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Jun. 7, 2011; Mar. 23, 2013>*

(2) No manufacturing manager shall engage in affairs, other than management of manufacturing in the relevant factory.

(3) No manufacturer of drugs, etc. or person who has obtained permission by item shall interfere with the management affairs of a manufacturing manager, nor refuse, without good cause, any request from a manufacturing manager for matters necessary for performing the affairs. *<Amended on Oct. 17, 2007>*

Article 37-2 (Education for Manufacturing Managers)

(1) A manufacturing manager shall regularly receive education for ensuring safety and effectiveness of drugs, etc. and managing manufacturing and quality thereof.

(2) If necessary to prevent any risk to public health, the Minister of Food and Drug Safety may order manufacturing managers to receive education referred to in paragraph (1). *<Amended on Mar. 23, 2013>*

(3) A manufacturing manager (including a replaced manufacturing manager where such replacement was notified pursuant to Article 40 (1) 3) shall receive education referred to in paragraph (1) within six months from the date he or she begins the manufacturing management affairs: Provided, That the same shall not apply where he or she received the relevant education within two years before becoming a manufacturing manager. *<Amended on Dec. 29, 2015; 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 specialized organization or institution as an institution offering education. *<Amended on Mar. 23, 2013>*

(5) An institution offering education designated under paragraph (4) (hereinafter referred to as "institution offering education for manufacturing managers") shall observe matters prescribed by Ordinance of the Prime Minister, such as issuing certificates of completion of education, preparing and retaining education records, etc. *<Newly Inserted on Jan. 28, 2015>*

(6) Except as provided in paragraphs (1) through (5), matters necessary for educating manufacturing managers, such as the details, hours, and methods of education, and education fees, and matters necessary for requirements and procedures for designating an institution offering education, operation thereof, revocation of such designation, etc. shall be prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 23, 2013; Jan. 28, 2015>*

[Previous Article 37-2 moved to Article 37-3 *<Jun. 7, 2011>*]

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

(1) A person who has obtained permission by item shall employ a physician, pharmacist, or oriental medicine pharmacist to perform the affairs of post-marketing safety management, such as re-reviewing 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 permission by item of drugs to be used for animals only may perform the affairs of post-marketing safety management after employing a veterinarian. *<Amended on Feb. 1, 2012; Mar. 23, 2013; Jan. 28, 2015>*

(2) A person who performs the affairs of safety management under paragraph (1) (hereinafter referred to as "safety manager") shall comply with the matters prescribed by Ordinance of the Prime Minister, regarding the safety management of drugs in distribution. *<Amended on Mar. 23, 2013>*

[Moved from Article 37-2 *<Jun. 7, 2011>*]

Article 37-4 (Education for Safety Managers)

(1) A safety manager shall regularly receive education on the affairs of safety management under Article 37-3 (1).

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

(3) A safety manager (including a replaced safety manager where such replacement is notified under Article 40 (1) 3) shall receive education prescribed in paragraph (1) within six months from the date he or she begins the affairs of safety management: Provided, That this shall not apply where he or she received the relevant education within two years before becoming a safety manager. *<Amended on Dec. 29, 2015; Dec. 2, 2016>*

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

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

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

Article 38 (Duties of Production Management of Drugs and Reporting Thereof)

(1) A manufacturer of drugs, etc. or a person who has obtained permission by item of drugs shall comply with the matters prescribed by Ordinance of the Prime Minister with respect to the manufacturing and quality management (including self-tests) of drugs, etc. and other production management thereof. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Jun. 7, 2011; Mar. 23, 2013>*

(2) A person who has obtained permission by item 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 on Oct. 17, 2007; Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Dec. 2, 2016>*

Article 38-2 (Drug Identification Mark)

(1) A person who has obtained permission by item of drugs in dosage form determined and publicly notified by the Minister of Food and Drug Safety shall place a mark on the drugs distinguishable from other drugs (hereinafter referred to as "identification mark") and shall file for registration of the identification mark with the Minister of Food and Drug Safety and distribute such drugs in the market.

(2) Where a person who had filed for registration of an identification mark pursuant to paragraph (1) modifies the identification mark, he or she shall file for registration of modification with the Minister of Food and Drug Safety.

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

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

Article 39 (Recall of Hazardous Drugs)

(1) Where any of the following persons becomes aware that drugs, etc. have any issues as to safety and effectiveness, in violation of Article 53 (1), 61 (including cases applicable mutatis mutandis in Article 66), or 62 (including cases applicable mutatis mutandis in Article 66), he or she shall without delay recall the drugs, etc. in distribution or take necessary measures for recall. In such cases, a person falling under any of the subparagraphs 1 through 3 shall in advance report a recall plan to the Minister of Food and Drug Safety: *<Amended on Jan. 28, 2015>*

1. A person who has obtained permission by item 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. Other persons prescribed by Ordinance of the Prime Minister, among persons eligible to distribute or handle drugs pursuant to this Act or other statutes.

(2) The Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a Si/Gun/Gu may reduce or exempt the administrative dispositions issued pursuant to Article 76 for persons who have obtained permission by item of drugs, quasi-drug manufacturers, importers of drugs, etc., pharmacy founders, and drug distributors, who conscientiously perform the recall or take measures necessary for the recall in accordance with paragraph (1), as prescribed by Ordinance of the Prime Minister. *<Amended on Oct. 17, 2007; Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

(3) Matters necessary for the ranking of risk and standards for risk assessment necessary for the recall of drugs, etc. under paragraph (1), recall plans or procedures for recall, and destruction of and follow-up measures for recalled drugs, etc. shall be prescribed by Ordinance of the Prime Minister. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Jun. 7, 2011; Mar. 23, 2013>*

Article 40 (Notification of Business Closure)

(1) Where a manufacturer of drugs, etc. or a person who has obtained permission by item falls under any of the following cases, he or she shall file a notification of such fact with the Minister of Food and Drug Safety within seven days: Provided, That he or she need not file a notification, where the period of business suspension is less than one month: *<Amended on Mar. 23, 2013; Dec. 2, 2016>*

1. Where he or she closes, or suspends the operation of, a factory or a place of contract manufacturing and distribution business;
2. Where he or she resumes the operation of a factory or a place of contract manufacturing and distribution business after suspension;
3. Where a manufacturing manager or a safety manager is replaced, or other matters prescribed by Ordinance of the Prime Minister are modified.

(2) Where a manufacturer of drugs, etc., or a person who has obtained permission by item intends to file a notification of business closure or business suspension under paragraph (1), he or she shall recall the drugs, etc. in distribution or take the necessary measures for recall under Article 39 or take other necessary measures as prescribed by Ordinance of the Prime Minister. *<Newly Inserted on Dec. 2, 2016>*

(3) Where a manufacturer of drugs, etc., or a person who has obtained permission by item files a notification of business resumption under paragraph (1) 2, he or she shall attach and submit the documents or data prescribed by Ordinance of the Prime Minister, such as the result of inspecting facilities in factories of drugs, etc. and the status of possession of drugs, etc., to the Minister of Food and Drug Safety: Provided, That where a manufacturer of drugs, etc. or a person who has obtained permission by item, whose period of business suspension is less than one year, files a notification of business resumption, the Minister of Food and Drug Safety may exempt the duty to submit documents or data. *<Newly Inserted on Dec. 2, 2016>*

(4) Upon receipt of a notification referred to in paragraph (1), the Minister of Food and Drug Safety shall examine the details of the notification and accept such notification if in compliance with this Act. *<Newly Inserted on Jan. 15, 2019>*

Article 41 (Preparation of Pharmacy Medication)

(1) When pharmacy founders intend to prepare pharmacy medications or dispensaries of medical institutions designated by the Minister of Health and Welfare intend to prepare medications, they shall file a notification of the relevant items with 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 the Mayor/Do Governor pursuant to the Medical Service Act, intends to prepare medications, it shall file a notification with the relevant Mayor/Do Governor. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

(2) Upon receipt of a notification referred to in paragraph (1), the head of a Si/Gun/Gu or the Mayor/Do Governor shall examine the details of the notification and accept such notification if in compliance with

this Act. *<Newly Inserted on Jan. 15, 2019>*

(3) 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 on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 15,2019>*

SECTION 2 Permission for Import of Drugs

Article 42 (Permission for Import of Drugs)

(1) A person who intends to engage in the business of importing drugs, etc. shall file a notification of import business with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister, and obtain permission from, or file a notification with, the Minister of Food and Drug Safety for each item, as prescribed by Ordinance of the Prime Minister. The same shall also apply where he or she intends to modify the matters permitted or notified. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 28, 2015>*

(2) Notwithstanding paragraph (1), the Minister of National Defense or a person who has filed a notification of import business pursuant to the former part of paragraph (1) (hereinafter referred to as "importer") may import drugs, etc. without obtaining permission, or filing a notification, by each item under paragraph (1) in any of following cases: *<Amended on Mar. 30, 2011; Mar. 23, 2013; Jan. 28, 2015>*

1. Where the Minister of National Defense intends to import drugs, etc, not produced domestically for any urgent military purpose, following prior-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 to import the drugs, etc. prescribed by Ordinance of the Prime Minister, including drugs, etc. for clinical trials.

(3) An importer shall secure necessary facilities, such as a business place, in compliance with the standards for facilities prescribed by Presidential Decree. *<Amended on Jan. 28, 2015>*

(4) None of the following persons shall file a notification of import 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 on Jan. 28, 2015; Oct. 24, 2017>*

1. A person falling under any of the subparagraphs of Article 5;
2. A person for whom one year has not elapsed since a business place is closed pursuant to Article 76: Provided, That the same shall not apply to any of the following cases:
   (a) A person recognized as capable of performing pharmaceutical affairs by a psychiatrist after being subject to closure for falling under subparagraph 1 or 3 of Article 5;
   (b) A person determined for termination of adult guardianship or limited guardianship by a family court after being subject to closure as he or she falls under subparagraph 2 of Article 5;
3. A person declared bankrupt and not yet reinstated;

(5) Articles 31 (7), (10) and (12), 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 permission by item" as "importers", respectively, and "factory or place of contract manufacturing and distribution business" as "business place", respectively. *<Amended on Oct. 17, 2007; Mar. 30, 2011; Jun. 7, 2011; Dec. 2, 2011; May 14, 2012; Mar. 18, 2014; Jan. 28, 2015; Mar. 13, 2015; Jan. 15, 2019>*

(6) Upon receipt of a notification referred to in paragraph (1), the Minister of Food and Drug Safety shall examine the details of the notification and accept such notification if in compliance with this Act. *<Newly Inserted on Jan. 15, 2019>*

(7) An importer who intends to import drugs, etc. prescribed by Ordinance of the Prime Minister among those for which he or she has obtained permission or filed a notification by item pursuant to paragraph (1) shall file for registration of matters prescribed by Ordinance of the Prime Minister, including the name, location, etc. of overseas factories (referring to factories located overseas for the manufacturing and quality management of drugs, etc.; hereinafter the same shall apply), with the Minister of Food and Drug Safety. *<Newly Inserted on Dec. 11, 2018; Jan. 15, 2019>*

(8) An importer who intends to modify any matter prescribed by Ordinance of the Prime Minister, among the matters registered pursuant to paragraph (7), shall file for registration of modification with the Minister of Food and Drug Safety; and where the importer modifies matters other than those prescribed by Ordinance of the Prime Minister, he or she shall file a notification of such modification with the Minister of Food and Drug Safety. *<Newly Inserted on Dec. 11, 2018; Jan. 15, 2019>*

(9) Matters necessary for notifications of import business, and the subject matters, standards, conditions, and management of permission by item or a notification by item prescribed in paragraph (1); and the procedures, methods, etc. for registration, registration of modification, and notifications of modification prescribed in paragraphs (7) and (8) shall be prescribed by Ordinance of the Prime Minister. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 30, 2011; Mar. 23, 2013; Jan. 28, 2015; Dec. 11, 2018; Jan. 15, 2019>*

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

(1) A person who intends to export, import, or carry into Korea by sea, drugs made from processed goods of animals and plants prescribed in 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 on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

(2) No person shall commit 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 distributing the horns of rhinoceros or the bones of tigers, or storing or displaying them for distribution;

2. Manufacturing or dispensing drugs using the horns of rhinoceros or the bones of tigers;

3. Distributing any drugs manufactured or dispensed using the horns of rhinoceros or the bones of tigers, or storing or displaying them for distribution.

SECTION 3 Distribution Business of Drugs

Article 44 (Distribution of Drugs)

(1) No person, other than pharmacy founders (including pharmacists or oriental medicine pharmacists working for the relevant pharmacy; hereafter in Article 47, 48, and 50, the same shall apply), shall distribute or obtain drugs for distribution: Provided, That the same shall not apply where a person who has obtained permission by item of drugs, or an importer, distributes drugs manufactured or imported to a person eligible to manufacture or distribute drugs according to this Act or where university students majoring in pharmacy dispense drugs to the extent prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended on Oct. 17, 2007; Dec. 29, 2015>*

(2) Notwithstanding paragraph (1), any of the following persons may distribute or obtain drugs for distribution: *<Amended on May 14, 2012; Dec. 2, 2016>*

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

1-2. A distributor of safe and readily available drugs who has been registered under Article 44-2 (limited to cases of distributing safe and readily available drugs referred to in Article 44-2 (1));

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

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

(1) A person who intends to distribute 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 ingredients, 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 as a distributor of safe and readily available drugs with the head of the competent Si/Gun/Gu.

(2) A person who intends to file for registration as a distributor 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 standards 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, and other matters.

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

(4) Where a distributor of safe and readily available drugs closes or suspends the business of distribution of safe and readily available drugs or resumes the suspended business, he or she shall file a notification thereof with the head of the competent Si/Gun/Gu: Provided, That the same shall not apply where the period of business suspension is less than one month.

(5) Matters necessary for filing for registration and filing for registration of modification pursuant to paragraphs (1) through (3) and those necessary for the methods, procedures, etc. for filing a notification of business closure, suspension, and resumption under paragraph (4) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

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

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

(2) If deemed necessary to prevent any risk to public health, the Minister of Health and Welfare may order a distributor of safe and readily available drugs (including his or her employees) to receive education on the safety assurance and quality management 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 educational institution.

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

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

A distributor of safe and readily available drugs shall observe the following matters:

1. The distributor shall manage his or her facilities and safe and readily available drugs to ensure that such drugs do not cause any risk to health and hygiene and their efficacy is not undermined;
2. The distributor shall thoroughly supervise his or her employees in order to prevent any incident related to health and hygiene;
3. The distributor shall observe the matters prescribed by Ordinance of the Ministry of Health and Welfare, such as the limit of quantity to distribute at one time, and age restriction on distribution;
4. The distributor shall observe other matters corresponding to subparagraphs 1 through 3 and prescribed by Ordinance of the Ministry of Health and Welfare.

Article 44-5 (Succession to Status of Sellers of Safe and Readily Available Drugs)

(1) Where a seller of safe and readily available drugs transfers his/her business and the transferee intends to succeed to the status of the former seller of safety and readily applicable drugs, he/she shall report such

fact to the head of a Si/Gun/Gu, as prescribed by Ordinance of the Ministry of Health and Welfare, within one month from the date of transfer.

(2) Upon receipt of a report under paragraph (1), the head of a Si/Gun/Gu shall review the details of the report and accept it if such report is consistent with this Act: Provided, That where a transferee fails to meet the registration standards under Article 44-2 (2) or to receive education on the safety assurance and quality management of safe and readily available drugs under Article 44-3 (1), the head of a Si/Gun/Gu shall not accept his/her report.

(3) Where the notification referred to in paragraph (1) is accepted, the transferee shall succeed to the status of a seller of safe and readily available drugs as of the date of transfer.

[Previous Article 44-5 moved to Article 44-6 *<Apr. 7, 2020>]*

Article 44-6 (Application Mutatis Mutandis)

(1) Articles 39 (1), 47 (1), 50 (1) and (3), 56 (2), 68-7, 69, 71, and 72 (2) shall apply mutatis mutandis to distributors of safe and readily available drugs registered under Article 44-2 (1). In such cases, "pharmacy founder" shall be construed as "distributor 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 distributors of safe and readily available drugs registered under Article 44-2 (1). In such cases, "pharmacy" shall be construed as "distributor of safe and readily available drugs". *<Amended on Dec. 2, 2016>*

[Moved from Article 44-5 *<Apr. 7, 2020>]*

Article 45 (Permission for Drug Distribution Business)

(1) A person who intends to become an herb druggist or drug wholesaler pursuant to Article 44 (2) 2 shall obtain permission from 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 permitted matters. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Jun. 7, 2011>*

(2) An herb druggist or drug wholesaler who intends to obtain permission pursuant to paragraph (1) shall have facilities classified as follows: *<Amended on Mar. 30, 2011; Mar. 18, 2014; Jan. 28, 2015>*

1. In cases of an herb druggist, a business place and other facilities meeting the standards for facilities prescribed by Presidential Decree;

2. In cases of a drug wholesaler, a business place, a warehouse, and other facilities meeting the standards for facilities prescribed by Presidential Decree. In such cases, the area of the warehouse shall be at least 165 square meters: Provided, That where he or she handles only imported drugs, reagents, or drug substances, the area of the warehouse shall be at least 66 square meters; where he or she handles only animal drugs, the area of the warehouse shall be at least 33 square meters; where he or she handles only herbal drugs, high pressure gases for medical purposes, and radiopharmaceuticals, the standards

for the area of warehouses shall not be applied.

(3) Permission for an herb druggist under paragraph (1) shall be granted to a person who has passed the examination for herb druggists prescribed by Presidential Decree only in districts prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

(4) An herb druggist permitted under paragraph (1) may distribute herbal drugs after mixing them in accordance with a prescription recorded in an established herbal drug book or with a prescription of an oriental medical doctor, at the request of a patient.

(5) A drug wholesaler permitted under paragraph (1) shall employ a pharmacist to manage the relevant affairs, and an herbal drug wholesaler shall employ any of the following persons to manage the relevant affairs: Provided, That the same shall not apply where the drug wholesaler who is a pharmacist directly manages the relevant affairs or where any of the following herbal drug wholesalers directly manages the relevant affairs: *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

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

(6) Where a drug wholesaler or herbal drug wholesaler intends to employ a person who manages the relevant affairs pursuant to paragraph (5), he or she shall file a notification with the head of a Si/Gun/Gu, as prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, the head of a Si/Gun/Gu shall examine the details of the notification and accept such notification if in compliance with this Act. *<Newly Inserted on Jun. 7, 2011; Jan. 15, 2019>*

(7) Matters necessary for the standards for and conditions and management of permission under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Jun. 7, 2011>*

(8) Notwithstanding paragraph (5), in cases of entrusting the affairs of 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 relevant affairs pursuant to paragraph (5): Provided, That in such cases, a person to whom distribution and management affairs are entrusted shall employ a person who manages the relevant affairs pursuant to paragraph (5), as prescribed by Ordinance of the Ministry of Health and Welfare. *<Newly Inserted on Dec. 29, 2015>*

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

None of the following persons shall be permitted as an herb druggist or drug wholesaler: *<Amended on Jun. 7, 2011>*

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

2. A person for whom one year has not passed after his or her permission was revoked pursuant to Article 76;

3. A medical institution founder (where the medical institution is a corporation, the executive officers and staff thereof) or a pharmacy founder;

4. A person declared bankrupt and not yet reinstated.

Article 47 (Order in Distribution of Drugs)

(1) Any 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 on Dec. 29, 2015>*

1. A person who has obtained permission by item 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) Distributing drugs to persons other than pharmacy founders; distributors of safe and readily available drugs; herb druggists; druggists or drug sellers referred to in Article 5 of the Addenda to the Pharmaceutical Affairs (Act No. 8365) (hereinafter referred to as “founder of pharmacy, etc."); other drug wholesalers; and other persons entitled to distribute drugs pursuant to this Act;

2. Notwithstanding subparagraph 1, a drug provider may retail or distribute drugs where he or she falls under any ground prescribed by Presidential Decree, such as cases for public interests;

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

(a) A drug wholesaler or a founder of pharmacy, etc. shall not purchase drugs from a person other than a drug provider: Provided, That this shall not apply where he or she purchases drugs from the founder of pharmacy, etc. who closed his or 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 or her pharmacy;

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

4. A drug wholesaler, a founder of pharmacy, etc., and other persons entitled to distribute 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 hazardous drugs, and compliance by drug wholesalers with the standards for quality management of drugs in distribution;

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

(2) No drug provider (including the representative, directors, or other employees of a corporation, or the employees of a non-corporation; hereafter in this Article, the same shall apply) 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 employed by the relevant pharmacy; hereafter in this Article, the same shall apply), medical personnel, medical institution founders (including the representative, directors, and other workers of a corporation; hereafter in this Article, the same shall apply), or persons employed by a medical institution for the purpose of sales promotion, such as adoption of drugs, inducement of prescription, and maintenance of transactions, nor have pharmacists, oriental medicine pharmacists, medical personnel, medical institution founders, or persons working for a medical institution provide economic benefits, etc. to the relevant pharmacy or medical institution: Provided, That the same shall not apply to the economic benefits, etc. within the extent prescribed by Ordinance of the Ministry of Health and Wealth, following consultation with the Minister of Food and Drug Safety, such as the provision of samples, support for symposiums, support for clinical trials, product presentation, discount in price and payment terms, and post-marketing survey (hereinafter referred to as "provision of samples, etc."). *<Newly Inserted on May 27, 2010; Mar. 23, 2013; Dec. 22, 2015; 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 transactions, nor assist the relevant pharmacy, etc. to acquire such economic benefits, etc.: Provided, That the same shall not apply to the economic benefits, etc. within 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 on May 27, 2010; Mar. 23, 2013; Dec. 29, 2015; Dec. 29, 2015>*

(4) No drug wholesaler shall distributes drugs, directly or through another drug wholesaler, to the medical institution or pharmacy with which he or she has any of the following affiliations: Provided, That the same shall not apply to herbal drugs: *<Newly Inserted on Jun. 7, 2011>*

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

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

   (c) If a drug wholesaler is a corporation, a person who de facto controls the relevant corporation (referring to a person who has contributed or owns the share exceeding 50/100 of the total amount of contributions, the total issued stock, or the total contributed shares of the relevant corporation, 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 an affiliated person referred to in item (c) is a corporation, an executive officer of the relevant corporation or a person who de facto controls the relevant corporation;

(e) If an affiliated person referred to in item (c) or (d) is an individual, his or her relatives within the second degree of consanguinity or affinity;

(f) A corporation which de facto controls drug wholesalers;

(g) A corporation de facto controlled by an affiliated person under this subparagraph;

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

2. Where a person who has any of the following affiliations 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 or her relatives within the second degree of consanguinity or affinity;

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

(c) If a medical institution founder is a corporation, a person who de facto controls the relevant corporation;

(d) If an affiliated person under item (c) is a corporation, an executive officer of the relevant corporation, and a person who de facto controls the relevant corporation;

(e) If an affiliated person under item (c) or (d) is an individual, his or her relatives within the second degree of consanguinity or affinity;

(f) A corporation which de facto controls a corporate medical institution;

(g) A corporation de facto controlled by an affiliated person under this subparagraph;

(h) Employees of a medical institution founder, a pharmacy founder, or an affiliated person under this subparagraph.

(5) Where a pharmacy founder or medical institution founder is to pay the purchase price of drugs to a drug provider, the payment shall be made within six months from the date of receiving the relevant drugs: Provided, That the same shall not apply to cases prescribed by Ordinance of the Ministry of Health and Welfare in consideration of the scale of the drug transactions, etc. where a pharmacy founder or medical institution founder is not deemed to have a superior bargaining position against a drug provider. <*Newly Inserted on Dec. 22, 2015*>

(6) Where a pharmacy founder or medical institution founder pays the purchase price of drugs to a drug provider after the period specified in paragraph (5), the interest shall be paid for the overdue period at an interest rate prescribed by the Minister of Health and Welfare within the limit of 20/100 per annum in consideration of economic situations, such as overdue interest rates applied by banks referred to in the

Banking Act. ? *<Newly Inserted on Dec. 22, 2015>*

(7) Where the purchase price of drugs referred to in paragraph (5) is paid with a bill or by a means of payment in place of a bill prescribed in the Fair Transactions in Subcontracting Act, Article 13 of that Act shall apply mutatis mutandis. In such cases, “prime contractor” shall be construed as “pharmacy founder or medical institution founder”, “subcontractor” as “drug provider”, “subcontract consideration” as “purchase price of drugs”, “60 days” as “six months”, “40/100” as “20/100”, and the “Fair Trade Commission” as the “Ministry of Health and Welfare”. *<Newly Inserted on Dec. 22, 2015>*

Article 47-2 (Submission of Expense Report on Details of Providing Economic Benefits)

(1) A drug provider shall prepare an expense report on economic benefits, etc. which he or 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 evidentiary 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 evidentiary data under paragraph (1). In such cases, a drug provider shall comply therewith unless there is good cause.

[Previous Article 47-2 moved to Article 47-3 *<Dec. 2, 2016>]*

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

(1) The Minister of Health and Welfare may designate a relevant specialized institution or organization as an institution for information management 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 drug distribution information, such as manufacturing, import, supply, and details of use of drugs and require it to perform such affairs. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

(2) Where a person who has obtained permission by item of drugs, an importer, or a drug wholesaler has supplied medical institutions, pharmacies, and drug wholesalers with drugs, he or she shall submit the 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 or 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, other public organizations, etc. to provide necessary data for efficient management of drug distribution information, and the State, local governments, other public organizations, etc. upon receipt of such request shall comply with such request, unless there is a compelling reason not to do so. 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 distribution and management of drugs. *<Amended on Feb. 29, 2008; Jan. 18, 2010; 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 on Feb. 29, 2008; Jan. 18, 2010>*

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

[Moved from Article 47-2 *<Dec. 2, 2016>]*

Article 48 (Prohibition of Distribution 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 permission by item of the drugs, etc., or an importer pursuant to Article 63 for the purpose of distribution of such drugs: Provided, That the same shall not apply to any of the following cases: *<Amended on Oct. 17, 2007; Feb. 29, 2008; Jan. 18, 2010>*

1. Where a pharmacy founder dispenses and distributes drugs according to prescriptions made by a physician, dentist, or oriental medical doctor, or pursuant to the proviso of Article 23 (3), the proviso of paragraph (6) of that Article, or to Article 4 of the Addenda to the amended Pharmaceutical Affairs Act (Act No. 4731);
2. Where a pharmacy founder opens and distributes herbal medications;
3. Where a person designated by the Minister of Health and Welfare opens and distributes drugs within the scope prescribed by Ordinance of the Ministry of Health and Welfare.

Article 49 (Restrictions on Products for Distribution by Drug Sellers)

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

Article 50 (Distribution of Drugs)

(1) No pharmacy founder or drug distributor shall distribute drugs at a place, other than his or 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 distribute any prescription drugs without prescriptions issued by a physician or dentist: Provided, That the same shall not apply where prescription drugs are distributed to any person who has opened a veterinary hospital under the Veterinarians Act, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended on Feb. 29, 2008; Jan. 18, 2010>*

(3) A pharmacy founder may distribute over-the-counter drugs without prescriptions issued by a physician or a dentist.

(4) Where a pharmacy founder distributes over-the-counter drugs, he or she may provide medication counselling therefor, if deemed necessary.

CHAPTER V-2 REGISTRATION OF DRUG PATENT AND PREVENTION OF DISTRIBUTION

SECTION 1 Registration of Drug Patent

Article 50-2 (Registration of Drug Patent)

(1) A person who has obtained permission by item referred to in Article 31 (2) and (3) or permission for modification referred to in paragraph (9) of the same Article (hereinafter referred to as “permission by item or permission for modification”) shall file an application for registration of a drug patent in the drug patent list (hereinafter referred to as “patent list”) in which the Minister of Food and Drug Safety registers and manages patents on drugs for which permission by item or permission for modification is granted (hereinafter referred to as “drug patent”).

(2) A person who intends to file an application for registration of a drug patent 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, along with a copy of the patent register, a 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 permission by item or permission for modification is granted or from the date the grant of the patent is registered pursuant to Article 87 of the Patent Act:

1. The 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 business place within Korea, referring to the personal information of a representative of the patentee who resides or has a business place within Korea);
4. Patent number;
5. Expiration date of the term 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 a drug patent pursuant to paragraph (1), may file an application for modification of the details of a registration application specified in paragraph (2) before the decision on such application is made: Provided, That in cases of adding claims, he or she shall file an application within the period for application referred to in paragraph (2).

(4) Where a drug patent, for which registration has been applied pursuant to paragraph (1) or the modification 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 term of the patent, and post them on the website for the public:

1. The drug patent shall pertain to any of the following:
   (a) Substance;
   (b) Dosage form;
   (c) Composition;
   (d) Medical usage;
2. The drug patent shall be directly related to matters for which permission by item or permission for modification of the relevant drug is granted;
3. An application for the drug patent shall be filed pursuant to Article 42 of the Patent Act before the date permission by item or permission for modification of the relevant drug is granted;
4. The drug patent shall not have expired by the expiration of the term of the patent, invalidation, relinquishment, etc.;
5. Permission by item or permission for modification of the relevant drug shall be effective.

(5) Where it is necessary to examine whether to meet the subject matters and requirements referred to in the subparagraphs of 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. for filing applications for registration of drug patents pursuant to paragraph (1) or applications for modification of the details of registration applications pursuant to paragraph (3) shall be prescribed by Ordinance of the Prime Minister.

Article 50-3 (Modification of Registered Information)

(1) A person who has a drug patent registered in the patent list after filing an application for registration of the drug patent pursuant to Article 50-2 (1) (hereinafter referred to as “registered patentee”) may file an application for modification 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 modification of the expiration date of the term 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 modification: Provided, That the Minister of Food and Drug Safety may grant a further period of up to 30 days for the modification upon application of the registered patentee.

(3) The Minister of Food and Drug Safety may modify or delete the registered information, where he or she checks the details of an application filed under paragraph (1) and such details are deemed appropriate. In such cases, the Minister of Food and Drug Safety shall in advance seek the opinions of interested parties, such as a patentee of a drug (hereinafter referred to as “patentee, etc. of a listed drug”), the drug

patent of which is registered in the patent list (hereinafter referred to as "listed drug"), or a person who has filed an application for permission by item or permission for modification of a drug, based on data about the safety and effectiveness of a listed drug.

(4) In any of the following cases, the Minister of Food and Drug Safety may modify 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 a patentee, etc. withdraws his or her consent;
2. Where the subject matters and requirements referred to in Article 50-2 (4) cease to be met;
3. Where a drug patent is registered by fraud or other improper means;

(5) Where the Minister of Food and Drug Safety modifies or deletes the registered information pursuant to paragraphs (3) and (4), he or she shall post it on the website for the public.

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

SECTION 2 Informing of Application for Permission by Item and Prohibition of Distribution

Article 50-4 (Informing of Application for Permission by Item)

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

1. Where the term of a registered patent expires;
2. Where an application for permission by item or permission for modification of a drug is filed to distribute the drug after the term of a registered patent expires;
3. Where a registered patentee and a patentee, etc. of a listed drug consent to not giving information;
4. Cases prescribed by Presidential Decree, corresponding to subparagraphs 1 through 3.

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

(3) Information 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 or her agent stated in the patent list.

(4) Information referred to in paragraph (1) or (2) shall be given within 20 days from the date an application for permission by item or permission for modification is filed. If the notice is not given within such period, the date a person who has filed an application for permission by item or permission for

modification informs a registered patentee or a patentee, etc. of a listed drug, whichever occurs later, shall be deemed the date of filing an application for permission by item or permission for modification.

(5) A person who has given information pursuant to paragraph (1) or (2) shall without delay submit a document evidencing the fact of giving such information 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 date of filing an application for permission, main ingredients, and dosage form of the informed drug (hereinafter referred to as "informed drug"), on the website for the public.

(6) Where information referred to in paragraph (1) or (2) is not given, the Minister of Food and Drug Safety shall not grant the relevant permission by item or permission for modification.

(7) Matters necessary for the methods, procedures, etc. for giving information under paragraph (1) shall be prescribed by Ordinance of the Prime Minister.

Article 50-5 (Application for Prohibition of Distribution)

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

1. An application for prohibition of distribution 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 shall be 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 regarding an informed drug before filing an application for prohibition of distribution:

1. A litigation to seek injunction against, 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 prohibition of distribution of the drug whose distribution has already been prohibited pursuant to Article 50-6 (1) shall not be additionally filed: Provided, That this shall not apply to an application for prohibition of distribution of an informed drug after an application for modification of the efficacy and effectiveness is filed pursuant to Article 31 (9).

(4) The Minister of Food and Drug Safety shall not grant permission by item or permission for modification of an informed drug until the period for filing an application for prohibition of distribution under paragraph (1) expires: Provided, That this shall not apply to any of the following cases:

1. Where there is a trial ruling under Article 162 of the Patent Act or a ruling under Article 189 of that Act that the drug for which prohibition of distribution was applied does not fall within the scope of the registered patent;

2. Where there is a trial ruling under Article 162 of the Patent Act or a ruling under Article 189 of that Act that the registered patent is invalid;

3. Where there is a decision under Article 43 of the Administrative Appeals Act and a ruling of a court against a litigation instituted under Article 3 of the Administrative Litigation Act that registration of a drug patent is illegal.

(5) Where there is a trial ruling or ruling against the trial ruling, decision, or ruling referred to in each subparagraph of paragraph (4) after such trial ruling, decision, or ruling, the Minister of Food and Drug Safety shall not grant permission by item or permission for modification of the informed drug, notwithstanding the proviso of paragraph (4).

(6) Matters necessary for the methods, procedures, etc. for filing applications for prohibition of distribution shall be prescribed by Ordinance of the Prime Minister.

Article 50-6 (Prohibition of Distribution)

(1) Where the Minister of Food and Drug Safety upon receipt of an application for prohibition of distribution under Article 50-5 (1) grants permission by item or permission for modification of the drug for which the application for prohibition of distribution was filed, he or she shall prohibit the distribution of such drug for nine months from the date the patentee, etc. of a listed drug is informed pursuant to Article 50-4 (hereinafter referred to as “date of receipt of information”), except in any of the following cases:

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

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

3. Where an 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 by fraud or other improper means;

5. Where at least two drugs are informed under Article 50-4 and an application for prohibition of distribution is filed only for some of the drugs, of which the following matters are same with those of the informed drugs (hereinafter referred to as “same drug”):

(a) Main ingredients and the content thereof;

(b) Dosage form;

(c) Dose regimen and dose;

(d) Efficacy and effectiveness;

6. Where the same drug with the drug, for which an application for prohibition of distribution is filed, can be distributed after permission by item or permission for modification has already been granted, based on the data on the safety and effectiveness of the listed drug;

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

8. Where a registered patent falls under Article 106 (1) or 106-2 (1) of the Patent Act or is subject to a petition for adjudication under Article 107 of that 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 is made before granting permission by item or permission for modification of the informed drug, the Minister of Food and Drug Safety shall prohibit the distribution of such drug for nine months from the date of receipt of information, notwithstanding paragraph (1).

(3) Prohibition of distribution referred to in paragraph (1) shall remain in effect by one of the following dates, whichever comes first:

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

2. The date a ruling is made that the drug for which an application for prohibition of distribution 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 any trial or litigation referred to in the subparagraphs of Article 50-5 (2) ended by the withdrawal or consent to withdrawal of a patentee, etc., reconciliation, rejection, etc.;

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

7. The date the period for permission by item or permission for modification of the listed drug expires;

8. The expiration date of the term of the registered patent;

The date a decision by the Fair Trade Commission or a trial ruling by a court is made that the patentee, etc. of a listed drug has violated Article 3-2 (1), 19 (1), or 23 (1) of the Monopoly Regulation and Fair Trade Act in connection with prohibition of distribution or permission for preferential distribution of items referred to in Article 50-7;

10. The date it is found that an application for prohibition of distribution has been filed by fraud or other improper means.

(4) Matters necessary for prohibition of distribution, procedure of extinction, etc. under paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

Article 50-6 (Prohibition of Distribution)

(1) Where the Minister of Food and Drug Safety upon receipt of an application for prohibition of distribution under Article 50-5 (1) grants permission by item or permission for modification of the drug for which the application for prohibition of distribution was filed, he or she shall prohibit the distribution of such drug for nine months from the date the patentee, etc. of a listed drug is informed pursuant to Article 50-4 (hereinafter referred to as “date of receipt of information”), except in any of the following cases:

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

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

3. Where an 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 by fraud or other improper means;

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

(a) Main ingredients and the content thereof;

(b) Dosage form;

(c) Dose regimen and dose;

(d) Efficacy and effectiveness;

6. Where the same drug with the drug, for which an application for prohibition of distribution is filed, can be distributed after permission by item or permission for modification has already been granted, based on the data on the safety and effectiveness of the listed drug;

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

8. Where a registered patent falls under Article 106 (1) or 106-2 (1) of the Patent Act or is subject to a petition for adjudication under Article 107 of that 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 is made before granting permission by item or permission for modification of the informed drug, the Minister of Food and Drug Safety shall prohibit the distribution of such drug for nine months from the date of receipt of information, notwithstanding paragraph (1).

(3) Prohibition of distribution referred to in paragraph (1) shall remain in effect by one of the following dates, whichever comes first: *<Amended on Dec. 29, 2020>*

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

2. The date a ruling is made that the drug for which an application for prohibition of distribution 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 any trial or litigation referred to in the subparagraphs of Article 50-5 (2) ended by the withdrawal or consent to withdrawal of a patentee, etc., reconciliation, rejection, etc.;

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

7. The date the period for permission by item or permission for modification of the listed drug expires;

8. The expiration date of the term of the registered patent;

9. The date a decision by the Fair Trade Commission or a trial ruling by a court is made that the patentee, etc. of a listed drug has violated Article 5 (1), 40 (1), or 45 (1) of the Monopoly Regulation and Fair Trade Act in connection with prohibition of distribution or permission for preferential distribution of items referred to in Article 50-7;

10. The date it is found that an application for prohibition of distribution has been filed by fraud or other improper means.

(4) Matters necessary for prohibition of distribution, procedure of extinction, etc. under paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

SECTION 3 Permission for Preferential Distribution of Items

Article 50-7 (Application for Permission for Preferential Distribution of Items)

(1) Where a person who shall give information pursuant to Article 50-4 files an application for permission by item or permission for modification of a drug, he or she may also file an application for permission to preferentially distribute drugs over the drugs meeting all of the following requirements (hereinafter referred to as “permission for preferential distribution of items”), with the Minister of Food and Drug Safety:

1. A drug shall be the same drug with the drug for which an application for permission for preferential distribution of items is filed;

2. A drug shall be the drug, the effective ingredients of which are identical to those of the listed drug, among the drugs for which an application for permission by item or permission for modification has been filed based on the data on safety and effectiveness of the listed drug.

(2) A person who intends to obtain permission for preferential distribution of items shall file a petition for any of the following trials before filing an application under paragraph (1):

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 the scope of rights pursuant to Article 135 of the Patent Act.

(3) A person who files a petition for a trial under the subparagraphs of paragraph (2) shall without delay inform the Minister of Food and Drug Safety of the matters prescribed by Ordinance of the Prime Minister, such as the patent trial number. The Minister of Food and Drug Safety may post the matters informed on the website for the public.

(4) A person who intends to obtain permission for preferential distribution of items shall submit an application for permission for preferential distribution of items, stating the following matters, to the Minister of Food and Drug Safety, along with the documents prescribed by Ordinance of the Prime Minister, such as a petition for trial referred to in the subparagraphs of paragraph (2):

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

Article 50-8 (Permission for Preferential Distribution of Items)

(1) Upon receipt of an application for permission for preferential distribution of items pursuant to Article 50-7, the Minister of Food and Drug Safety shall grant permission for preferential distribution of items together with permission by item or permission for modification of a drug, where the applicant meets all of the following requirements:

1. The applicant shall be the first applicant among those who have filed an application for permission by item or permission for modification of the drug required to be informed 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. The applicant 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 rights in the patent: Provided, That a person who received a trial ruling or ruling after nine months have passed from the date of receipt of information shall be excluded therefrom;

3. The applicant shall meet any of the following requirements and receive a trial ruling or ruling pursuant to subparagraph (2):

(a) The applicant shall be the first one who files a petition for trial under the subparagraphs of Article 50-7 (2) (hereafter in this subparagraph, referred to as “first trial”);

(b) The applicant shall file a petition for trial within 14 days from the date of filing the first trial;

(c) The applicant shall receive a trial ruling or ruling under subparagraph 2, prior to a person who meets the requirements under item (a) or (b).

(2) Where the Minister of Food and Drug Safety grants permission for preferential distribution of items pursuant to paragraph (1), he or she shall post the matters prescribed by Ordinance of the Prime Minister, such as the main ingredients or dosage form of the drug for which permission for preferential distribution of items is granted, or the date of permission, on the website for the public.

Article 50-9 (Prohibition of Distribution of Same Drugs)

(1) Where the Minister of Food and Drug Safety grants permission for preferential distribution of items pursuant to Article 50-8 (1), he or she may prohibit the distribution of the drugs meeting all of the following requirements during the period referred to in paragraph (2) when granting permission by item or permission for modification of such drugs:

1. A drug shall be the same drug with the drug for which permission for preferential distribution of items is granted;

2. A drug shall be the drug, the effective ingredients of which are identical to those of the listed drug, among the drugs for which an application for permission by item or permission for modification has been filed, based on the data on safety and effectiveness of the listed drug.

(2) The period of prohibition of distribution under paragraph (1) shall be nine months from the date a person who has obtained first permission for preferential distribution of items of a drug may distribute the drug: Provided, That in cases of a drug for which an application for health care benefits has been filed pursuant to Article 41 (1) 2 of the National Health Insurance Act, the period may be extended by up to two months.

(3) Matters necessary for the methods, procedures, etc. for prohibition of distribution referred to in paragraphs (1) and (2) shall be prescribed by Ordinance of the Prime Minister.

Article 50-10 (Extinction of Effect of Prohibition of Distribution of Same Drug)

(1) Prohibition of distribution referred to in Article 50-9 (1) shall cease to be effective on any of the following dates, whichever comes earlier:

1. The date permission by item or permission for modification of a drug for which permission for preferential distribution of items is granted, ceases to be effective;

2. The date a registered patent ceases to be effective due to the expiration of the registered patent or the finalization, 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 permission for preferential distribution of items).

(2) The Minister of Food and Drug Safety shall terminate the effect of prohibition of distribution under Article 50-9 (1) in any of the following cases. In such cases, the Minister of Food and Drug Safety shall hear in advance the opinions of the person who has obtained permission for preferential distribution of items:

1. Where a ruling to revoke 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 a person fails to distribute the drug for which permission for preferential distribution of items is granted, within two months from the date such drug may be distributed, without good cause;

3. Where a decision by the Fair Trade Commission or a trial ruling by a court is made that a person who has obtained permission for preferential distribution of items violates Articles 3-2 (1), 19 (1), or 23 (1) of the Monopoly Regulation and Fair Trade Act in connection with prohibition of distribution or permission for preferential distribution of items;

4. Where a person has obtained permission for preferential distribution of items by fraud or other improper means.

(3) A person who has filed an application for permission by item or permission for modification of the same drug with those for which permission for preferential distribution of items is granted, or any other interested party may provide the information that permission for preferential distribution of items falls under paragraph (1) or (2) to the Minister of Food and Drug Safety.

(4) Matters necessary for the extinction of the effect of prohibition of distribution and the methods, procedures, etc. for providing information by the interested parties pursuant to paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

Article 50-10 (Extinction of Effect of Prohibition of Distribution of Same Drug)

(1) Prohibition of distribution referred to in Article 50-9 (1) shall cease to be effective on any of the following dates, whichever comes earlier:

1. The date permission by item or permission for modification of a drug for which permission for preferential distribution of items is granted, ceases to be effective;
2. The date a registered patent ceases to be effective due to the expiration of the registered patent or the finalization, 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 permission for preferential distribution of items).

(2) The Minister of Food and Drug Safety shall terminate the effect of prohibition of distribution under Article 50-9 (1) in any of the following cases. In such cases, the Minister of Food and Drug Safety shall hear in advance the opinions of the person who has obtained permission for preferential distribution of items: *<Amended on Dec. 29, 2020>*

1. Where a ruling to revoke 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 a person fails to distribute the drug for which permission for preferential distribution of items is granted, within two months from the date such drug may be distributed, without good cause;
3. Where a decision by the Fair Trade Commission or a trial ruling by a court is made that a person who has obtained permission for preferential distribution of items violates Articles 5 (1), 40 (1), or 45 (1) of the Monopoly Regulation and Fair Trade Act in connection with prohibition of distribution or permission for preferential distribution of items;
4. Where a person has obtained permission for preferential distribution of items by fraud or other improper means.

(3) A person who has filed an application for permission by item or permission for modification of the same drug with those for which permission for preferential distribution of items is granted, or any other interested party may provide the information that permission for preferential distribution of items falls under paragraph (1) or (2) to the Minister of Food and Drug Safety.

(4) Matters necessary for the extinction of the effect of prohibition of distribution and the methods, procedures, etc. for providing information by the interested parties pursuant to paragraphs (1) through (3)

shall be prescribed by Ordinance of the Prime Minister.

SECTION 4 Impact Assessment

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 prohibition of distribution and permission for preferential distribution of items 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 agencies, education and research institutions, etc. to provide necessary data. In such cases, the heads of the relevant administrative agencies, education and research institutions, etc. upon receipt of the request for the provision of data shall comply therewith, unless there is good cause.

(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 standards, methods, procedures, etc. for the impact assessment referred to in paragraphs (1) through (4) shall be prescribed by Ordinance of the Prime Minister.

Article 50-12 (Management 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, permission for preferential distribution of items, etc.;
3. Providing education 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 upon receipt of such request shall comply therewith, unless there is good cause:

1. The State or local governments;

2. Public institutions or public organizations;

CHAPTER VI HANDLING OF DRUGS

SECTION 1 Standards and Verification

Article 51 (The 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 and publicly announce the Korean Pharmacopoeia following deliberation by the Central Pharmaceutical Affairs Advisory Committee. *<Amended on Jun. 7, 2011; Mar. 23, 2013>*

(2) The Korean Pharmacopoeia shall consist of Parts I and II: Drug substances that are frequently used and the primary medications shall be mainly listed in Part I, and the mixed medications of drugs and the drugs, etc. not listed in Part I shall be mainly listed in Part II. *<Amended on Jun. 7, 2011>*

Article 52 (Standards for Drugs)

(1) With regard to biological medications and drugs which are not listed in the Korean Pharmacopoeia, the Minister of Food and Drug Safety may determine the nature, state, quality and storing methods, and other necessary standards after hearing the opinion of the Central Pharmaceutical Affairs Advisory Committee. *<Amended on Jun. 7, 2011; Mar. 23, 2013>*

(2) Where deemed necessary to prevent any risk to health and hygiene, the Minister of Food and Drug Safety may determine the manufacturing method, properties, performance, quality, and storing method of quasi-drugs and other necessary standards therefor after hearing the opinion of the Central Pharmaceutical Affairs Advisory Committee. *<Amended on Mar. 23, 2013>*

Article 52-2 (Fact-Finding Surveys and Research on Safe Use of Drugs by Specific Groups)

(1) The Minister of Health and Welfare and the Minister of Food and Drug Safety may conduct a fact-finding survey on 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 permission by item 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 permission by item, upon receipt of such instruction, shall comply therewith.

Article 53 (Drugs under National Lot Release)

(1) A person who intends to distribute or to display, keep, or store, for distribution, 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 undergoing the examination, verification, etc. of the data on manufacturing and quality management of the drugs: *<Amended on Mar. 23, 2013>*

1. Biological medications;
2. Drugs liable to be altered or spoiled in quality;
3. Deleted. *<Dec. 11, 2018>*

(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 on Mar. 23, 2013>*

Article 54 (Radiopharmaceuticals)

The Minister of Food and Drug Safety may determine matters necessary for manufacturing, import, etc. of radiopharmaceuticals after consultation with the Minister of Science and ICT. *<Amended on Jun. 7, 2011; Mar. 23, 2013; Jul. 26, 2017>*

Article 55 (Addictive and Habit-Forming Drugs)

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

SECTION 2 Handling of Drugs

Article 56 (Labeling on Drug Containers)

(1) A person who has obtained permission by item of drugs 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, part of the following information may be omitted or only part of the following information may be indicated, as prescribed by Ordinance of the Prime Minister: *<Amended on May 14, 2012; Mar. 23, 2013; Dec. 2, 2016>*

1. The trade name and address of a person who has obtained permission by item of drugs or an importer (in cases of contract manufacturing, including the trade name and address of a factory);
2. The product name;
3. The manufacturing number and the user-by date or expiration date;
4. The weight, capacity, or number of articles;
5. Labeling on 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 other labeling on 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 permission by item and certificate of notification by item: Provided, That ingredients prescribed by Ordinance of the Prime Minister, such as ingredients included in small quantity except preservatives, may be excluded;

8. The letter "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 distributes drugs directly to consumers, such as a pharmacy founder, shall indicate the prices of drugs on the containers or packages of such drugs, as prescribed by the Minister of Health and Welfare.

Article 57 (Labeling on Outside Packages)

If information listed in the subparagraphs of Article 56 (1) and paragraph (2) of that Article, which has been indicated on the immediate containers or packages of drugs, is not visible because it is obstructed by the outside containers or packages, the same information shall be also indicated on the outside containers or packages. *<Amended on Jun. 7, 2011>*

Article 58 (Labeling on Package Inserts)

The following information shall be indicated in package inserts for drugs: *<Amended on Feb. 29, 2008; Jan. 18, 2010; Jun. 7, 2011; Mar. 23, 2013>*

1. Dose regimen, dose, and other precautions necessary for use or handling;

2. As for drugs listed in the Korean Pharmacopoeia, labeling on the package inserts, containers, or packages of drugs prescribed by the Korean Pharmacopoeia;

3. As for drugs, the standards for which are determined under Article 52 (1), labeling on the package inserts, 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 through 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 on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

Article 60 (Information Prohibited from Labeling)

None of the following information shall be indicated in package inserts for drugs or labels of containers or packages of drugs: *<Amended on Oct. 17, 2007; Dec. 11, 2018>*

1. False or misleading information with regard to the relevant drug;
2. Efficacy or effectiveness for which permission or permission for modification has not been obtained or a notification or a notification of modification has not been filed under Article 31 (2), (3) or (9) or 41 (1);
3. Dose regimen, dose, or period of use which is dangerous to health and hygiene.

Article 61 (Prohibition of Distribution)

(1) No one shall distribute, or store or display the following drugs for distribution: *<Amended on Oct. 17, 2007; Jun. 7, 2011; Dec. 11, 2018>*

1. Drugs in violation of Articles 56 through 60 or fake drugs;
2. Drugs manufactured or imported in violation of Articles 31 (1) through (3) and (9), 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 distribute, or store or display for distribution, articles in which such information is indicated or advertised.

Article 61-2 (Prohibition against Arranging and Advertising Illegal Distribution of Drugs)

(1) No one shall arrange or advertise the distribution of drugs in violation of Article 44 or 50 (1) and (2) and shall arrange or advertise the distribution of drugs referred to in the subparagraphs of Article 61 (1) or products carrying misleading indication or advertisement prescribed in paragraph (2) of that Article.

(2) Where it is necessary to investigate the distribution of drugs using the information and communications network under Article 2 (1) 1 of the Act on Promotion of Information and Communications Network Utilization and Information Protection (hereafter in this Article, referred to as “information and communications network”) or any violation of paragraph (1), the Minister of Food and Drug Safety may request submission of the necessary data from providers of information and communications services defined in Article 2 (1) 3 of the Act on Promotion of Information and Communications Network Utilization and Information Protection or mail order brokers referred to in Article 20 of the Act on the Consumer Protection in Electronic Commerce (hereafter in this Article referred to as “information and communications service providers, etc.”). In such cases, information and communications service providers, etc. upon receipt of a request for submission of data shall comply with such request, unless there is good cause.

(3) Upon discovering the distribution of drugs using the information and communications network or any violation of paragraph (1), information and communications service providers, etc. shall immediately inform the Minister of Food and Drug Safety of such fact.

(4) Matters necessary for the scope of and procedures for a request for data submission referred to in paragraph (2), the methods for informing referred to in paragraph (3), etc. shall be prescribed by Ordinance of the Prime Minister.

Article 62 (Prohibition of Manufacturing)

No one shall distribute any of the following drugs nor shall manufacture, import, store, or display them for the purpose of distribution: *<Amended on Oct. 17, 2007; Jun. 7, 2011; Mar. 23, 2013; Dec. 11, 2018>*

1. Drugs listed in the Korean Pharmacopoeia, whose properties, performance, or quality does not meet the standards specified in the Korean Pharmacopoeia;
2. Drugs for which permission or permission for modification has been obtained or a notification or a notification of modification has been filed under Articles 31 (2), (3), or (9) or 41 (1), but whose ingredients or quantities (if active ingredients are unclear, the essence thereof or the outline of manufacturing methods) are different from the contents for which permission or permission for modification has been obtained or a notification or a notification of modification has been filed;
3. Drugs the standards for which are determined under Article 52 (1), but which do not meet such standards;
4. Drugs, all or part 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 may cause any risk to health and hygiene, or which are manufactured at a place where the manufacturing facilities fail to meet the standards prescribed by Presidential Decree;
9. Drugs which are likely to cause any risk to health and hygiene, due to unsanitary containers or packages;
10. Drugs whose containers or packages may lead users to misunderstand the method of using them;
11. Drugs falling under Article 76 (1) 4.

Article 63 (Sealing)

If a manufacturer of drugs, a person who has obtained permission by item, or an importer distributes drugs manufactured or imported by oneself, he or 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 or she distributes them to a drug manufacturer, or a person who has obtained permission by item. *<Amended on Oct. 17, 2007; Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

Article 64 (Safety Containers or Packages)

(1) Where a person who has obtained permission by item of drugs or an importer distributes drugs manufactured or imported by oneself, he or 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 the drugs are distributed to drug manufacturers or persons who have obtained permission by item. *<Amended on Oct. 17, 2007>*

(2) The scope of items for which safety containers or packages shall be used and the standards, etc. for safety containers or packages shall be prescribed by Ordinance of the Prime Minister. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

SECTION 3 Quasi-Drugs

Article 65 (Labeling on Containers of Quasi-Drugs)

(1) A manufacturer or importer of quasi-drugs shall indicate the following information on the containers or packages of quasi-drugs: Provided, That part of the following matters may not be stated or only part of the following matters may be indicated, as prescribed by Ordinance of the Prime Minister: *<Amended on Mar. 23, 2013; Dec. 2, 2016; Oct. 24, 2017>*

1. Names of quasi-drugs;
2. The 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. The manufacturing number and the expiration date;
5. The name of all ingredients stated in the certificate of permission by item and certificate of notification by item: 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 other labeling on containers or packages in accordance with such standards;
7. The letters of "quasi-drug";
8. Other information prescribed by Ordinance of the Prime Minister.

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

Article 65-2 (Labeling on Outside Packages)

Where the information referred to in the subparagraphs of Article 65 (1) and paragraph (2) of that Article, which has been indicated on the immediate containers or packages of quasi-drugs, is not visible on the outside containers or packages, the same information shall be also indicated on such outside containers or

packages.

[Previous Article 65-2 moved to Article 65-4 *<Oct. 24, 2017>]*

Article 65-3 (Labeling on Package Inserts)

Where there are package inserts for quasi-drugs, the following information shall be indicated thereon:

1. Dose regimen, dose, and other precautions for use or handling;
2. For quasi-drugs listed in the Korean Pharmacopoeia, labeling on the package inserts, containers, or packages of quasi-drugs prescribed by the Korean Pharmacopoeia;
3. For quasi-drugs, the standards for which are determined under Article 52 (2), labeling on the package inserts, containers, or packages of quasi-drugs in accordance with such standards;
4. Other information prescribed by Ordinance of the Prime Minister, which are necessary to ensure the safe use of quasi-drugs.

Article 65-4 (Precautions in Indications)

Information provided for in Articles 65, 65-2, and 65-3 shall be indicated on places which are readily visible compared to 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 on Mar. 23, 2013; Oct. 24, 2017>*

[Moved from Article 65-2 *<Oct. 24, 2017>]*

Article 66 (Application Mutatis Mutandis)

@Articles 60, 61, 62 and 63 (Articles 60, 61, and 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"; "Article 31 (1) through (3) and (9)" as "Article 31 (4) and (9)"; “Article 31 (2), (3) and (9)” respectively as “Article 31 (4) and (9); “Article 52 (1)” as “Article 52 (2)”; and “Articles 56 through 60” as “Articles 65 and 65-2 through 65-4, and Article 60 which is applied mutatis mutandis pursuant to Article 66.” *<Amended on Feb. 1, 2012; Oct. 24, 2017; Dec. 11, 2018>*

SECTION 4 Pharmaceutical Organizations

Article 67 (Organization)

Manufacturers of drugs, etc., persons who have obtained permission by items, 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 on Oct. 17, 2007>*

SECTION 5 Advertisement of Drugs

Article 68 (Prohibition of Exaggerated Advertisement)

(1) Names, manufacturing methods, efficacy, or performance of drugs, etc. shall not be advertised falsely or unduly.

(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) Drugs, etc. shall not be advertised by news articles, photographs, or designs that suggest efficacy or performance, or other suggestive methods.

(4) Documents or designs which suggest induced abortion shall not be used with respect to drugs.

(5) Names, manufacturing methods, efficacy, or performance of drugs, etc. shall not be advertised without obtaining permission or permission for modification or filing a notification or a notification of modification under Article 31 (2) through (4) and (9) or 42 (1). *<Amended on Oct. 17, 2007; Dec. 11, 2018>*

(6) None of the following drugs shall be advertised: Provided, That the same shall not apply to cases prescribed by Ordinance of the Prime Minister, including advertising drugs for preventing infectious diseases defined in subparagraphs 2 through 12 of Article 2 of the Infectious Disease Control and Prevention Act and placing advertisements on professional medical media targeting professionals, etc. in medicine and pharmacy: *<Newly Inserted on Oct. 24, 2017>*

1. Prescription drugs;
2. Over-the-counter drugs with the same dosage form, administration route, and content of active ingredient per unit dosage form as prescription drugs;
3. Drug substances.

(7) The methods of advertisement of drugs, etc. and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Oct. 24, 2017>*

Article 68-2 (Deliberation on Advertisement)

(1) Where a drug manufacturer, a person who has obtained permission by item, or an importer intends to advertise drugs manufactured or imported by oneself, he or she shall undergo deliberation by the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 23, 2013>*

(2) The Minister of Food and Drug Safety may entrust an association incorporated pursuant to Article 67 with the affairs concerning deliberation on advertisement of drugs under paragraph (1). *<Amended on Mar. 23, 2013>*

(3) Matters necessary for procedures and method for deliberation on advertisement under paragraph (1), raising of an objection against the results of deliberation, modification of the details of deliberation, indication of the results of deliberation, etc. shall be prescribed by Ordinance of the Prime Minister. *<Amended on Jun. 7, 2011; Mar. 23, 2013>*

SECTION 6 The Korea Institute of Drug Safety and Risk Management

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 providing a variety of information on drug safety, such as side effects of drugs, etc., information on permission by item, and information on notification by item (hereinafter referred to as "drug safety information").

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

(3) The articles of association of the Institute of Drug Safety and Risk Management shall include the following matters: *<Newly Inserted on Dec. 11, 2018>*

1. Purposes;
2. The name;
3. The location of the principal office;
4. Matters concerning assets;
5. Matters concerning the executive officers and employees;
6. Operation of the board of directors;
7. The scope, contents, and execution of business;
8. Accounting;
9. The methods of public announcement;
10. Modification of the articles of association;
11. Other important matters concerning the operation of the Institute of Drug Safety and Risk Management.

(4) Where the Institute of Drug Safety and Risk Management intends to modify any matter stated in the articles of association, it shall obtain authorization therefor from the Minister of Food and Drug Safety. *<Newly Inserted on Dec. 11, 2018>*

(5) Except as provided 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. *<Amended on Dec. 11, 2018>*

(6) Other matters necessary for the organization, operation, etc. of the Institute of Drug Safety and Risk Management shall be prescribed by Presidential Decree. *<Amended on Dec. 11, 2018>*

Article 68-4 (Projects)

The Institute of Drug Safety and Risk Management shall conduct the following projects entrusted by the Minister of Food and Drug Safety pursuant to Article 84 or other statutes and regulations; projects for the relief of injury from side effects of drugs entrusted pursuant to Article 86 (5); and for-profit projects

prescribed by Presidential Decree with regard to drug safety information: *<Amended on Mar. 23, 2013; Mar. 18, 2014; May 18, 2015>*

1. Investigating and identifying the causal relationship of side effects of drugs, such as pharmaceutical mishaps;
2. Establishing a drug safety information management system to collect and manage drug safety information;
3. Collecting, analyzing, assessing, managing, and providing drug safety information;
4. Conducting investigation, research, education, and publicity aimed at developing and utilizing drug safety information;
5. Other projects entrusted under this Act or other statutes and regulations.

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 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 a 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 modifications to such business plan and budget bill. *<Amended on 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 request any of the following institutions or persons to provide data regarding drug safety information. In such cases, an institution or a person upon receipt of a request shall comply with such request, unless there is good cause: *<Amended on 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 permission by item 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 or she may request the provision of data including personal

information, such as sensitive information prescribed in Article 23 of the Personal Information Protection Act and personally identifiable information (including resident registration numbers) prescribed in Article 24 of that Act. In such cases, the institution or person upon receipt of such request shall provide data after deleting the parts by which individual identification is possible. *<Amended on Jan. 28, 2015>*

(3) Notwithstanding paragraph (2), where the Minister of Food and Drug Safety approves that it is deemed necessary to combine and analysis data possessed by multiple number of institutions and persons, the president of the Institute of Drug Safety and Risk Management may collect data including the parts by which individual identification is possible for the combination of data. In such cases, the president shall, without delay, delete the parts by which personal identification is possible, after the combination of data, and shall make the deleted parts not restored or regenerated. *<Newly Inserted on Jan. 28, 2015>*

(4) No data provided pursuant to paragraphs (1) through (3) shall be used for any purpose other than that of such request. *<Newly Inserted on Jan. 28, 2015>*

(5) The Minister of Food and Drug Safety may regularly check whether the president of the Institute of Drug Safety and Risk Management complies with paragraphs (3) and (4) and may take necessary measures, such as dismissal, if he or she fails to comply with the paragraphs. *<Newly Inserted on Jan. 28, 2015>*

Article 68-8 (Reporting Side Effects)

(1) Where a manufacturer of drugs, etc., a person who has obtained permission by item of drugs, an importer, or a drug wholesaler becomes aware of an hazardous 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 drugs, etc. prescribed by Ordinance of the Prime Minister, he or she shall report such events to the president of the Institute of Drug Safety and Risk Management, as determined by the Minister of Food and Drug Safety. *<Amended on 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, or death prescribed by Ordinance of the Prime Minister, he or she shall report such events to the president of the Institute of Drug Safety and Risk Management, as prescribed by the Minister of Food and Drug Safety. *<Amended on 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 reported under paragraphs (1) and (2), as prescribed by the Minister of Food and Drug Safety. *<Amended on Mar. 23, 2013>*

Article 68-9 (Duty of Confidentiality)

No person who is or was an executive officer or employee of the Institute of Drug Safety and Risk Management shall divulge any confidential information he or she has become aware of in the course of performing the 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 “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 on Mar. 23, 2013; Mar. 18, 2014>*

1. Matters concerning judgment, etc. of side effects and risk probabilities of drugs, etc.;
2. Matters concerning identification of the causal relationship of side effects of drugs, etc. and identification of the causes of pharmaceutical mishaps, etc.;
3. Matters concerning the relief of injury caused by drugs, such as benefits for relief of injury, under Article 86-3 (1).

(2) The Deliberative Council shall be comprised of at least 10 but less than 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, and shall include at least one person, respectively, from among the following persons: *<Amended on Mar. 23, 2013>*

1. A person with expertise 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 in forensic medicine who is qualified as a judge, prosecutor, or attorney-at-law;
4. A public official of a relevant central administrative agency prescribed by Presidential Decree.

(4) Deleted. *<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 on Mar. 18, 2014>*

(6) The organization and operation of the Deliberative Council and working committees 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 or she shall report such fact to the Minister of Food and Drug Safety without delay.

(3) The president of the Institute of Drug Safety and Risk Management may have a drug epidemiological investigator enter a pharmacy, a medical institution, a factory, warehouse, shop, or office in which drugs, etc. are manufactured, stored, or handled, and other places that it is deemed necessary to investigate, to investigate relevant books, documents, or other articles, or make inquiries to relevant persons about drugs, etc. In such cases, the drug epidemiological investigator shall carry an identification indicating his or her authority and documents stating the matters prescribed by Presidential Decree, such as the period and scope of an investigation, persons in charge of the investigation, and relevant statutes and regulations, and show them to relevant persons. *<Amended on 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 procedures, methods, etc. for investigations or inquiries under paragraph (3) shall be prescribed by the Framework Act on Administrative Investigations, except as provided in this Act or other statues and regulations concerning epidemiological investigations of drugs. *<Newly Inserted on Dec. 29, 2015>*

CHAPTER VII SUPERVISION

Article 69 (Reporting and Inspections)

(1) The Minister of Health and Welfare, the Minister of Food and Drug Safety (including the head of an agency under his/her jurisdiction prescribed by Presidential Decree), the Mayor/Do Governor, or the head of a Si/Gun/Gu may give any of the following directions: *<Amended on Oct. 17, 2007; Feb. 29, 2008; Jan. 18, 2010; Jun. 7, 2011; Mar. 30, 2013; Jul. 30, 2013; Mar. 13, 2015; Oct. 24, 2017; Apr. 7, 2020>*

1. Requesting the submission of necessary documents or other data from pharmacy founders; medical institution founders; manufacturers of drugs, etc.; persons who have obtained permission by item of drugs; importers; distributors; registered patentees; patentees, etc. of a listed drug; persons who have obtained permission for preferential distribution of items; persons who have obtained approval for clinical trial protocols; institutions conducting clinical trials; institutions conducting the analysis of clinical trial samples; institutions conducting non-clinical studies; and other persons engaged in handling drugs, etc.;
2. Having the relevant public officials access pharmacies; medical institutions; factories, warehouses, shops, or offices that manufacture, store, or handle drugs, etc.; institutions conducting clinical trials; institutions conducting the analysis of clinical trial samples; institutions conducting non-clinical studies; places where registered patentees, patentees, etc. of a listed drug, or persons who have obtained permission for preferential distribution of items conduct the relevant affairs; places where drugs, etc. are

handled for clinical trials; or other places where drugs, etc. are handled for business, to inspect the relevant facilities, relevant books or documents, or other articles, or to inquire of the relevant persons;

3. Collecting articles in a minimum quantity necessary for quality inspections of articles and drugs, etc. which are suspected to fall under Article 71 (1).

(2) A public official who has access and conducts an inspection under paragraph (1) shall carry an identification indicating such authority and documents stating the matters prescribed by Presidential Decree, such as the period and scope of an investigation, persons in charge of the investigation, and relevant statutes and regulations, and shall show them to relevant persons. *<Amended on 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 on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

(4) The procedures, methods, etc. for inspections or inquiries under paragraph (1) 2 shall be prescribed by the Framework Act on Administrative Investigations, except as provided in this Act. *<Newly Inserted on Dec. 29, 2015>*

Article 69-2 (Informing Relevant Agencies)

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

1. The disposition of prohibiting the distribution of drugs pursuant to Article 50-6 (1) and (2) and the extinction of the effect of prohibition of distribution under paragraph (3) of that Article;

2. Permission for preferential distribution of items and the extinction of the effect of prohibition of distribution of the same drug under Article 50-10 (1) and (2);

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

Article 69-3 (Reporting 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 timing for 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 distribution of the relevant drug between a person who has obtained permission by item or permission for modification of the listed drug or a patentee, etc. of the listed drug, and a person who has filed an application for permission by item or permission for modification of the informed drug;

2. The agreement on acquisition and extinction of permission for preferential distribution of items between a person who has obtained permission by item or permission for modification of the listed drug or a patentee, etc. of the listed drug, and a person who has filed an application for permission by item or permission for modification of the informed drug;

3. The agreement on acquisition and extinction of permission for preferential distribution of items among the persons who have filed an application for permission by item or permission for modification of the informed drug.

Article 69-4 (Corrective Order)

Where pharmacy founders, persons who have obtained permission by item of drugs, importers, drug distributors, and other persons entitled to distribute 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 any violation for a specified period: *<Amended on Dec. 2, 2016; Oct. 24, 2017>*

1. Where they fail to comply with the matters necessary for management of a pharmacy under Article 21 (3);
2. Where they fail to comply with the matters necessary for the establishment of distribution systems of drugs, etc. and maintenance of order in distribution under Article 47 (1);
3. Where they fail to prepare an expense report under Article 47-2 (1) or fail to retain the relevant expense report, books related thereto, or evidentiary data;
4. Where they fail to indicate the prices of drugs on the containers or packages, in violation of Article 56 (2) (including cases applied mutatis mutandis pursuant to Article 44-6 (1)) or 65 (2).

Article 69-5 (On-Site Inspections at Overseas Manufacturing Factories)

(1) The Minister of Food and Drug Safety may access and inspect overseas manufacturing factories (hereafter in this Article, referred to as “on-site inspection”) after undergoing prior consultation with the relevant importer, the manager of the overseas manufacturing factories, or the government of the exporting country, in any of the following cases:

1. Where the Minister of Food and Drug Safety deems it necessary to conduct an on-site inspection to prevent any risk of imported drugs, etc. (hereafter in this Article, referred to as "imported drugs, etc.");
2. Where the Minister of Food and Drug Safety deems it necessary to verify the safety information on imported drugs, etc. collected domestically and internationally.

(2) Where overseas manufacturing factories refuse an on-site inspection without good cause or where the findings of an on-site inspection indicate potential risk of imported drugs, etc., the Minister of Food and Drug Safety may suspend import, order an inspection, or requests correction regarding the imported drugs, etc. of the relevant overseas manufacturing factories, or may revoke the registration of the relevant overseas manufacturing factories (hereafter in this Article, referred to as “suspension, etc. of import”).

(3) For imported drugs, etc. that become subject to any measure prescribed in paragraph (2), such as suspension, etc. of import, where the relevant importer, the manager of the overseas manufacturing factory, or the government of the exporting country identifies the causes of potential risk and suggests improvement measures or where it is deemed that the relevant imported drugs, etc. cause no risk as a

result of an on-site inspection, etc., the Minister of Food and Drug Safety may revoke any measure that has been taken, such as suspension, etc. of import. In such cases, an on-site inspection may be conducted if it is necessary to verify matters subject to improvement.

(4) Matters necessary for on-site inspections, measures such as suspension, etc. of import, and the procedures, methods, etc. for revocation thereof under paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

Article 70 (Order to Commence Business)

(1) If it is recognized that drug manufacturers, persons who have obtained permission by item of drugs, pharmacy founders, or drug distributors cause or are likely to cause remarkable impediment in the purchase of drugs through joint suspension of production and distribution of drugs, or collective business suspension or closure, the Minister of Health and Welfare, the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a Si/Gun/Gu may order them to produce drugs or commence their business. *<Amended on Oct. 17, 2007; Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

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

Article 71 (Order of Destruction)

(1) The Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a Si/Gun/Gu may order persons who have obtained permission by item 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 distribute or handle drugs pursuant to this Act or other statutes to destroy the drugs, etc. which have been distributed, stored, displayed, manufactured, or imported in violation of Articles 53 (1), 61 (including cases applied mutatis mutandis in Article 66), and 62 (including cases applied mutatis mutandis in Article 66) or bad drugs, etc. or the raw materials and materials thereof, etc. in a manner that prevents risk to public health or to take other necessary measures. *<Amended on Oct. 17, 2007; Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

(2) When it is deemed that any drug, etc. actually causes or is likely to cause any risk to public health, the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a Si/Gun/Gu may order persons who have obtained permission by item 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 distribute or handle drugs pursuant to this Act or other statutes, to recall and destroy such drug, etc. in distribution or to take other necessary measures. *<Amended on Oct. 17, 2007; Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

(3) Where any person upon 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, the Mayor/Do

Governor, or the head of a Si/Gun/Gu may require relevant public officials to recall and destroy the relevant articles or to take other necessary measures. *<Amended on Mar. 23, 2013>*

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

(5) Matters necessary for the ranking of risk and standards for risk assessment of drugs, etc., recall and destruction thereof, and other measures under paragraph (2) shall be prescribed by Ordinance of the Prime Minister. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

Article 72 (Announcement of Recall of Drugs)

(1) Upon receipt of a report on a plan for recall of drugs, etc. under the latter part of Article 39 (1), the Minister of Food and Drug Safety may order persons who have obtained permission by item of drugs, quasi-drug manufacturers, or importers of drugs, etc. to announce the recall plan: Provided, That he or she shall issue an order for announcement if the use of a relevant drug, etc. causes risk prescribed by Ordinance of the Prime Minister, such as serious side effects impossible to cure completely or side effects temporarily or medically possible to cure completely. *<Amended on Oct. 17, 2007; Feb. 1, 2012; Mar. 23, 2013>*

(2) Where the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a Si/Gun/Gu has issued an order to recall and destroy drugs, etc. in distribution or to take other necessary measures pursuant to Article 71 (2), he or she shall order persons who have obtained permission by item 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 distribute or handle drugs pursuant to this Act or other statutes, to announce such fact. *<Amended on Oct. 17, 2007; Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

(3) A person upon receipt of an order for announcement under paragraphs (1) and (2) shall make an announcement by any of the following methods, depending upon the ranking of risk under Article 71 (5): *<Newly Inserted on Feb. 1, 2012>*

1. Broadcasting, daily newspapers, or their equivalents;
2. Medical or pharmaceutical journals, or their equivalents;
3. The relevant company’s website, or its equivalents.

(4) Matters necessary for announcement referred to in paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister. *<Amended on Feb. 1, 2012; Mar. 23, 2013>*

Article 73 (Inspection Orders and Test and Inspection Institutions)

(1) The Minister of Food and Drug Safety or the Mayor/Do Governor may order manufacturers of drugs, etc., persons who have permission by item of drugs, or importers to undergo an inspection of drugs, etc. which are manufactured or imported or for which permission by item or a notification by item is granted or filed, from a testing 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 "testing and inspection institution"). *<Amended on Mar. 23, 2013; Jul. 30, 2013>*

(2) Deleted. *<Jul. 30, 2013>*

(3) Deleted. *<Jul. 30, 2013>*

(4) Deleted. *<Jul. 30, 2013>*

Article 73-2 Deleted. *<Jul. 30, 2013>*

Article 73-3 Deleted. *<Jul. 30, 2013>*

Article 74 (Order for Improvement)

Where 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 deteriorated, unclean, or damaged so that the drugs, etc. manufactured by using such facility are likely to fall under any of the subparagraphs of Article 62 (including cases applied 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 permission by item of drugs, importers, distributors, institutions conducting clinical trials, institutions conducting the analysis of clinical trial samples, and institutions conducting non-clinical studies to improve such facility or to suspend the use of all or part of such facility until the improvements have been completed. *<Amended on Oct. 17, 2007; Jun. 7, 2011; Mar. 23, 2013; Jul. 30, 2013; Jan. 28, 2015; Oct. 24, 2017>*

Article 75 (Order to Replace Managers)

If a manager of manufacturing business of drugs, etc. or a manager of a pharmacy violates this Act or an order issued pursuant to this Act, or if such manager is considered inappropriate as a manager, the Minister of Food and Drug Safety may order the relevant manufacturer to replace the manager of the manufacturing business, and the head of a Si/Gun/Gu may order the relevant pharmacy founder to replace the manager of the pharmacy. *<Amended on Mar. 23, 2013>*

Article 75-2 (Corrective Orders)

Where a pharmacy founder violates Article 47 (5) through (7), the Minister of Health and Welfare and the head of a Si/Gun/Gu may order him or her to correct the relevant violation by a specified period of up to three months, as prescribed by Ordinance of the Ministry of Health and Welfare.

Article 76 (Revocation of Permission and Suspension of Business)

(1) If a manufacturer of drugs, etc.; a person who has obtained permission by item of a drug; a person who has filed for registration of drug substances; an importer; a person who has obtained approval of a clinical trial protocol; 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 permission by item of a drug, person who has filed for registration of drug substances, importer, or person who has obtained approval of a clinical trial protocol; close his or her place of contract manufacturing and distribution business or factory (limited only to where a notification has been filed pursuant to Article 31 (4); hereafter the same shall apply in subparagraph 1 of Article 77); close his or her business place (limited only to where a notification has been filed pursuant to Article 42 (1); hereafter the same shall apply in subparagraph 1 of Article 77); issue an order to prohibit the manufacturing or import of items; or issue an order to fully or partially suspend the 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 in cases falling under subparagraph 4, if it is deemed that the relevant business entity is not liable and the purpose of permission or a notification is attainable by modifying the ingredients, prescription, etc. of the relevant drugs, etc., only the modification of ingredients, prescription, etc. may be ordered: *<Amended on Oct. 17, 2007; May 27, 2010; Mar. 30, 2011; Jun. 7, 2011; Feb. 1, 2012; Mar. 23, 2013; Aug. 13, 2013; Jan. 28, 2015; Mar. 13, 2015; Dec. 22, 2015; Oct. 24, 2017; Dec. 11, 2018; Jan. 15, 2019; Apr. 7, 2020>*

1. Where he or she falls under any of the subparagraphs of Article 5 (limited to an importer in cases falling under subparagraph 5): Provided, That the same shall not apply where the representative of a corporation falls under any of such provisions and is replaced within six months;
2. Where it is found that he or 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 the same shall not apply where the representative of a corporation falls under any of such provisions and is replaced within six months;
2-2. Where he or she who makes a private qualification registration under Article 20 (2) by fraud or other improper means;
2-3. Where a person obtains permission or permission for modification or makes a report or report on modification under Article 31 (1) through (4) or (9) by fraud or other improper means;
2-4. Where he or she fails to obtain permission by item or to file a notification by item, in violation of Article 31 (2) or (3);
2-5. Where he or she fails to obtain permission for modification or to file a notification of modification, in violation of Article 31 (9);
2-6. Where he or she files for registration of drug substances under Article 31-2 (1) and (3) (including cases applied mutatis mutandis pursuant to Article 42 (5)), files for registration of modification, or files a report on modification, by fraud or other improper means;
2-7. Where he or she fails to file for registration of modification of, or to file a report on modification of, drug substances under Article 31-2 (3) (including cases applied mutatis mutandis pursuant to Article 42 (5));
2-8. Where approval of a plan for a clinical trial under Article 34 (1) is obtained or approval for modification thereof is obtained by fraud or other improper means;

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

4. Where he or she manufactures, imports, or distributes drugs, etc. which caused or are likely to cause any risk to the public health, or drugs, etc. which are regarded as having no efficacy;

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

5-2. Where he or she fails to obtain permission or permission for modification for each item or to file a notification or a notification of modification for each item, in violation of Article 42 (1);

5-3. Where he or she files for registration or registration of modification or files a notification of modification regarding overseas manufacturing factories referred to in Article 42 (7) or (8), by fraud or other improper means;

5-4. Where he or she fails to file for registration or registration of modification or files a notification of modification, in violation of Article 42 (7) or (8);

5-5. Where he or she obtains permission under Article 43 (1) by fraud or other wrongful means;

5-6. Where he or she who has obtained transit or transshipment permission under Article 45 (1)by fraud or other improper means;

5-7. Where he or she offers any economic benefits, etc., in violation of Article 47 (2);

5-8. Where he or she who has filed an application for permission by item or permission for modification distributes a drug before the expiration of the term of a registered patent, in order to distribute such drug after the registered patent expires, in violation of Article 50-4 (1) 2;

5-9. Where he or she distributes drugs, the distribution of which has been prohibited under Article 50-6 (1) or (2) or 50-9 (1);

5-10. Where he or she indicates any information prescribed in the subparagraphs of Article 60 on the package inserts, containers, or packages of drugs, in violation of that Article;

5-11. Where he or she distributes any drug prescribed in the subparagraphs of Article 62 or manufactures, imports, stores, or displays such drug for distribution purposes, in violation of that Article;

5-12. Where he or she violates an order prescribed in Articles 71 (1) and (2) and 72 (1) and (2);

6. Where a pharmacy founder receives a disposition of suspension of qualifications as a pharmacist or oriental medicine pharmacist under Article 79 (2);

7. Where he or she fails to comply with a corrective order referred to in Article 75-2.

(2) Paragraph (1) shall also apply where the facilities of a person prescribed in paragraph (1) are not in compliance with the standards for facilities provided for in Articles 20 (3), 31 (1) and (4), 42 (3), and 45 (2). *<Amended on Oct. 17, 2007>*

(3) Among the standards for administrative dispositions under paragraphs (1) and (2), the standards for administrative dispositions, including the revocation of permission, notifications, registration, and approval, and the suspension of business, against a manufacturer of drugs, etc., a person who has obtained permission by item of a drug, a person who has filed for registration of drug substances, an importer, and a

person who has obtained approval of clinical trial protocols shall be prescribed by Ordinance of the Prime Minister; and the standards for administrative dispositions, including the revocation of licenses, registration, and permission, and the suspension of qualifications or business, against a pharmacist, an oriental medicine pharmacist, a pharmacy founder, or a drug distributor shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended on Mar. 23, 2013; Oct. 24, 2017>*

Article 76-2 (Revocation of Designation of Institutions Conducting Clinical Trials)

(1) If an institution conducting clinical trials, an institution conducting the analysis of clinical trial samples, or an institution conducting non-clinical studies 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 may revoke the designation of such institution or order it to fully or partially suspend business for up to nine months: Provided, That in cases falling under subparagraphs 1, 2, 2-2, or 5 (in cases falling under subparagraphs 2 and 2-2, limited to cases of intention or gross negligence), he or she shall revoke the designation of such institution: *<Amended on Mar. 23, 2013; Jul. 30, 2013; Jan. 28, 2015; Oct. 24, 2017; Jun. 12, 2018; Dec. 11, 2018>*

1. Where designation has been made by fraud or other improper means;
2. Where a clinical trial report or an analysis report of clinical trial samples referred to in Article 34-2 (3) 5 has been falsely prepared or issued, or the records on clinical trials have been falsely prepared;
2-2. Where a non-clinical study report referred to in Article 34-3 (3) has been falsely prepared or issued;
3. Where the requirements for designation referred to in Article 34-2 (1) and (5) 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 the designation is revoked.

(3) Where an institution conducting clinical trials under Article 34-2 fails to comply with the matters to be observed under paragraph (3) of the same Article, where it is deemed that such liability is attributable to the person responsible for conducting clinical trials, the Minister of Food and Drug Safety may order the head of the relevant institution conducting clinical trials to replace the person responsible for conducting clinical trials or exclude him or her from clinical trials for a period not exceeding nine months. *<Newly Inserted on Apr. 7, 2020>*

(4) The standards for administrative dispositions prescribed in paragraph (1) and (3) shall be prescribed by Ordinance of the Prime Minister. *<Amended on Mar. 23, 2013; Apr. 7, 2020>*

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

(1) The head of a Si/Gun/Gu may revoke the registration of a distributor of safe and readily available drugs in any of the following cases: Provided, That he or she shall revoke the registration in cases falling

under any of subparagraphs 1 and 3 through 6: *<Amended on Dec. 29, 2015>*

1. Where the distributor has filed for registration by fraud or other improper means;

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

3. Where the distributor fails to meet the standards for registration referred to in Article 44-2 (2);

4. Where the distributor fails to file for registration of modification, in violation of Article 44-2 (3), or has filed for such registration by fraud or other improper means;

5. Where the distributor fails to receive education, in violation of Article 44-3 (1);

6. Where the distributor fails to observe the matters to be observed by distributors of safe and readily available drugs, in violation of Article 44-4 (limited to cases where such violations are committed at least three times a year);

7. Where the distributor 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 the distributor distributes drugs at a non-designated place, in violation of Article 50 (1);

9. Where the distributor fails to comply with a request to submit documents or data prescribed in Article 69 (1) 1 or rejects, interferes with, or evades the access, inspection, inquiry, or collection under Article 69 (1) 2 or 3;

10. Where the distributor fails to comply with an order of destruction, etc. issued under Article 71 (1) or an order for recall and destruction issued under paragraph Article 71 (2), or rejects, obstructs, or evades the measures taken for recall, destruction, etc. under paragraph (3) of that Article;

11. Where the distributor fails to comply with an order for announcement prescribed in Article 72 (2).

(2) A person whose registration has been revoked under paragraph (1) shall be not be re-registered as a distributor of safe and readily available drugs within one year from the date his or her registration was revoked under paragraph (1).

Article 77 (Hearings)

The Minister of Health and Welfare, the Minister of Food and Drug Safety, the 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 on Oct. 17, 2007; Feb. 29, 2008; Jan. 18, 2010; Jun. 7, 2011; May 14, 2012; Mar. 23, 2013; Jan. 28, 2015>*

1. Revocation of permission, approval, and registration, closure of a place of contract manufacturing and distribution business, factory, or business place, or issuance of orders to prohibit the manufacturing or import of items 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, or Sis/Guns/Gus (Gus refer 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 on Mar. 23, 2013>*

(2) Pharmaceutical inspectors shall be appointed by the Minister of Health and Welfare, the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a Si/Gun/Gu from among the members of the Ministry of Health and Welfare, the Ministry of Food and Drug Safety, Cities/Dos, or Sis/Guns/Gus. *<Amended on Mar. 23, 2013>*

(3) Qualifications and appointment of pharmaceutical inspectors and other necessary matters shall be prescribed by Ordinance of the Prime Minister following consultation with the Minister of Health and Welfare. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

Article 79 (Revocation of Pharmacist or Oriental Medicine Pharmacist 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 or her license. *<Amended on Feb. 29, 2008; 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 or her license or order the suspension of qualifications as a pharmacist or oriental medicine pharmacist for a specified period of up to one year: *<Amended on Feb. 29, 2008; Jan. 18, 2010; Oct. 24, 2017>*

1. When he or she violates the statutes and regulations concerning pharmaceutical affairs or violates the standards for ethics prescribed by Ordinance of the Ministry of Health and Welfare;
2. When he or she forges or alters relevant documents or demands drug expenses by fraud or other improper means;
3. When he or she fails to comply with an order referred to in Article 79-2 (2) without good cause.

(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 qualifications as a pharmacist or oriental medicine pharmacist for a specified period of up to one year: *<Amended on May 27, 2010>*

1. Where he or she has been employed by a person disqualified as a pharmacy founder and performs the affairs of a pharmacist or oriental medicine pharmacist;
2. Where he or she receives any economic benefit, etc. in violation of Article 47 (3).

(4) If a pharmacist or oriental medicine pharmacist fails to make a report as referred to in Article 7 (1), the Minister of Health and Welfare may suspend the effect of license until such report is made. *<Newly Inserted on Apr. 7, 2020>*

(5) 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 on Feb. 29, 2008; Jun. 13, 2008; Jan. 18, 2010; Apr. 7, 2020>*

(6) A disposition of suspension of qualifications under paragraph (2) or (3) shall not be issued after five years (seven years in cases of the suspension of qualifications under paragraph (2) 2) from the date any ground therefor occurs: 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 on Dec. 2, 2016; Apr. 7, 2020>*

Article 79-2 (Requests for Disposition of Revocation of License or Suspension of Qualifications by the Pharmaceutical Association and the Oriental Pharmacy Association)

(1) Where a pharmacist or oriental medicine pharmacist is deemed to fall under any of the following subparagraphs, the head of the Pharmaceutical Association or the head of the Oriental Pharmacy Association may request any of the following dispositions by the Minister of Health and Welfare, after undergoing deliberations and decisions by the Ethics Committee of the Pharmaceutical Association or the Oriental Pharmacy Association:

1. In cases of falling under any ground for disqualification prescribed in subparagraphs 1 and 3 of Article 5: Revocation of a license;
2. In cases of violating the standards for ethics prescribed in Article 79 (2) 1: Suspension of qualifications.

(2) Where the head of the Pharmaceutical Association or the head of the Oriental Pharmacy Association requests a disposition of revocation of a license against any pharmacist or oriental medicine pharmacist pursuant to paragraph (1) 1, the Minister of Health and Welfare may order the relevant pharmacist or oriental medicine pharmacist to undergo inspections by a medical specialist regarding whether he or she falls under any ground for disqualification prescribed in subparagraphs 1 and 3 of Article 5.

Article 80 (Renewal of License, Permit, and Certificate of Registration)

A person who has obtained a pharmacist license or an oriental medicine pharmacist license, a person who has filed registration of establishment of a pharmacy, a distributor of safe and readily available drugs, or a person who has obtained permission for drug distribution business shall renew his or her license, permit, certificate of registration, etc. as prescribed by Ordinance of the Ministry of Health and Welfare; and a person who has obtained permission for manufacturing business of drugs, etc. or has filed a notification of contract manufacturing and distribution business shall renew such certificate, as prescribed by Ordinance of the Prime Minister.

Article 81 (Disposition of Penalty Surcharges Imposed in Lieu of Disposition of Business Suspension)

(1) If a manufacturer of drugs, etc., a person who has obtained permission by item of a drug, an importer, a pharmacy founder, or a drug distributor is subject to a disposition of business suspension prescribed in Article 76, the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a Si/Gun/Gu may impose a penalty surcharge not exceeding one billion won (100 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 qualifications as a pharmacist or oriental medicine pharmacist prescribed in Article 79 (2) 2 is subject to a disposition of business suspension under Article 76 (1) 5, the penalty surcharge in lieu thereof shall be imposed to not exceed three times the amount. *<Amended on Oct. 17, 2007; Jun. 7, 2011; Mar. 23, 2013; Jan. 15, 2019>*

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

(3) If necessary to impose 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 on Mar. 23, 2013; Dec. 11, 2018>*

1. Taxpayers' personal information;
2. The purpose of use;
3. Data on sales that forms the standards 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, the 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 delinquent national taxes are collected or pursuant to the Act on the Collection of Local Administrative Penalty Charges, as prescribed by Presidential Decree: Provided, That where it is impracticable to impose a disposition to suspend business pursuant to Article 76 (1) or (2) due to business closure, etc. under Article 40, the penalty surcharges shall be collected in the same manner as delinquent national taxes are collected or pursuant to the Act on the Collection of Local Administrative Penalty Charges. *<Amended on Mar. 23, 2013; Aug. 6, 2013; Mar. 24, 2020>*

(5) In order to collect a penalty surcharge in arrears pursuant to paragraph (4), the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a Si/Gun/Gu may request the submission of any of the following data from the relevant person prescribed in the following. In such cases, a person upon receipt of such request shall comply with it, unless there is a compelling reason not to do so: *<Newly Inserted on Dec. 11, 2018>*

1. A certified copy of a building register referred to in Article 38 of the Building Act: The Minister of Land, Infrastructure and Transport;

2. A certified copy of a cadastre referred to in Article 71 of the Act on the Establishment, Management, etc. of Spatial Data: The Minister of Land, Infrastructure and Transport;

3. A certified copy of a motor vehicle register referred to in Article 7 of the Motor Vehicle Management Act: The Mayor/Do Governor.

(6) 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 collection agency belongs. *<Amended on Dec. 11, 2018>*

Article 81-2 (Imposition of Penalty Surcharges for Manufacturing of Harmful Drugs)

(1) With respect to a manufacturer of drugs, a person who has obtained permission by item, or an importer, who is subject to a disposition of revocation of permission; an order to close a place of contract manufacturing and distribution business or a business place; an order to fully suspend business for at least three months; or an order to partially suspend business for at least six months pursuant to Article 76 (1) for violating Article 31 (2), (3) or (9) or 42 (1), subparagraph 3 of Article 60, or Article 62, the Minister of Food and Drug Safety may impose a penalty surcharge of not more than 5/100 of the production or import amount.

(2) The Minister of Food and Drug Safety shall take into account each of the following matters when imposing a penalty surcharge pursuant to paragraph (1):

1. The details and severity of violations;

2. The duration and frequency of violations;

3. The amount of profits acquired from violations.

(3) The standards and procedures for imposing penalty surcharges prescribed in paragraphs (1) and (2), and other necessary matters shall be prescribed by Presidential Decree.

(4) Where a person required to pay a penalty surcharge prescribed in paragraph (1) fails to pay the penalty surcharge by the payment deadline, the Minister of Food and Drug Safety shall collect an additional charge equivalent to 3/100 per annum of the penalty surcharge in arrears starting from the day following the payment deadline.

(5) Where a person required to pay a penalty surcharge prescribed in paragraph (1) fails to pay the penalty surcharge by its payment deadline, the Minister of Food and Drug Safety shall demand the payment by specifying a period; and where the person fails to pay the penalty surcharge and the additional charge prescribed in paragraph (4) within the specified period, the Minister of Food and Drug Safety shall collect them in the same manner as delinquent national taxes are collected.

(6) Article 81 (3) and (5) shall apply mutatis mutandis to a request for provision of information and data necessary to impose and collect penalty surcharges prescribed in paragraph (1).

Article 82 (Fees)

(1) Each of the following persons shall pay a fee, as prescribed 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: *<Amended on Feb. 8, 2017>*

1. A person who intends to obtain a pharmacist or oriental medicine pharmacist license 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 distributor 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 drug distribution information;
6. A person who intends to apply for the national examinations for a pharmacist license or an oriental medicine pharmacist license, preliminary examinations for a pharmacist license, 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 or she shall pay a fee as prescribed by Ordinance of the Prime Minister. The same shall also apply to permission, renewal, registration, notification, or approval, or the modification of the matters prescribed by Ordinance of the Prime Minister: *<Amended on Mar. 13, 2015>*

1. Applying for permission, renewal, registration, notification, approval, designation, or a preliminary examination;
2. Determining the standards for new products;
2-2. Filing an application for registration of a drug patent, modification of the registered matters, prohibition of distribution, or permission for preferential distribution of items under Article 50-2, 50-3, 50-5 or 50-7;
2-3. Filing an application for modification of the registered matters during the extension 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) A 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.

CHAPTER VIII SUPPLEMENTARY PROVISIONS

Article 83 (Subsidization from National Treasury)

The Minister of Health and Welfare and the Minister of Food and Drug Safety may subsidize research funds for the manufacturers of drugs, etc. who have contributed to export, or for institutions, etc. that contribute to the national health by performing research projects on the safety of drugs, etc., as prescribed by Presidential Decree. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>*

Article 83-2 (Training of Professional Personnel)

(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 professional personnel.

(2) In order to train professional personnel 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 and research institutions, 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 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 related 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 administrative agency, the 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 83-3 (Specialized Pharmacist)

(1) A pharmacist who intends to become a specialized pharmacist shall obtain accreditation from the Minister of Health and Welfare after completing the curricula prescribed by Presidential Decree.

(2) No person other than persons who have obtained the recognition of qualifications as a specialized pharmacist under paragraph (1) shall indicate specialized subjects.

(3) Matters concerning the accreditation of the qualifications of specialized pharmacists and the specialized subjects shall be prescribed by Presidential Decree.

[Previous Article 83-3 moved to Article 83-4 *<Apr. 7, 2020>*]

Article 83-4 (Comprehensive Drug Safety Management Plans)

(1) The Minister of Food and Drug Safety shall formulate a comprehensive plan for drug safety management (hereinafter referred to as “comprehensive plan") for the safe management of drugs every five years in consultation with the heads of the relevant central administrative agencies.

(2) A comprehensive plan shall contain each of the following matters:

1. The basic objectives of and direction for implementation of drug safety management policies;
2. A business plan for drug safety management, and the methods of financing;
3. Education and public campaign necessary for drug safety management;
4. Investigation, research, and development regarding drug safety management;
5. Other matters deemed necessary by the Minister of Food and Drug Safety for drug safety management.

(3) In order to implement a comprehensive plan, the Minister of Food and Drug Safety shall formulate an implementation plan for drug safety management (hereinafter referred to as “implementation plan") each year in consultation with the heads of the relevant central administrative agencies.

(4) Where the Minister of Food and Drug Safety formulates a comprehensive plan or an implementation plan, he or she shall inform the heads of the relevant central administrative agencies and the heads of local governments.

(5) Where necessary to formulate a comprehensive plan or an implementation plan, the Minister of Food and Drug Safety may request the provision of necessary data from the heads of the relevant central administrative agencies, the heads of local governments, or the heads of relevant institutions or organizations.

(6) Matters necessary to formulate and implement a comprehensive plan or an implementation plan shall be prescribed by Ordinance of the Prime Minister.

Article 83-4 (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 related 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 administrative 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.

[Moved from Article 83-3; Previous Article 83-4 moved to Article 83-5 *<Apr. 7, 2020>*]

Article 83-5 (Establishment and Operation of Integrated Drug Information System)

(1) The Minister of Food and Drug Safety shall establish and operate an integrated drug information system (hereinafter referred to as “integrated information system") to comprehensively manage the affairs necessary for safety management with respect to the clinical trials, permission by item, manufacturing, import, distribution, use, etc. of drugs, etc.

(2) The Minister of Food and Drug Safety may request the provision of information necessary to establish and operate an integrated information system (including sensitive information prescribed in Article 23 of the Personal Information Protection Act and personally identifiable information prescribed in Article 24 of that Act; In such cases, the relevant information shall be protected in accordance with the Personal Information Protection Act) from the following institutions, organizations, or persons. In such cases, any institution, organization, or person upon receipt of such request shall comply with it, unless there is good cause:

1. The State or local governments;

2. Public institutions or public organizations;

3. Pharmacy founders; medical institution founders; manufacturers of drugs, etc., persons who have obtained permission by item, importers, or distributors; registered patentees; patentees, etc. of listed drugs; persons who have obtained permission for preferential distribution of items; persons who have obtained approval of clinical trial protocols; institutions conducting clinical trials; institutions conducting the analysis of clinical trial samples; institutions conducting non-clinical studies; and other persons prescribed by Ordinance of the Prime Minister who are engaged in handling drugs, etc.

(3) The Minister of Food and Drug Safety may entrust the affairs necessary for maintaining and managing an integrated information system to the Institute of Drug Safety and Risk Management. In such cases, the Minister of Food and Drug Safety may fully or partially subsidize the expenses incurred in maintaining and managing the integrated information system.

(4) Matters necessary for establishment and operation of an integrated information system, requests for the provision of information, entrustment, etc. under paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

Article 83-5 (Comprehensive Drug Safety Management Plans)

(1) The Minister of Food and Drug Safety shall formulate a comprehensive plan for drug safety management (hereinafter referred to as “comprehensive plan") for the safe management of drugs every five years in consultation with the heads of the relevant central administrative agencies.

(2) The comprehensive plan shall include the following:

1. The basic objectives of and direction for implementation of drug safety management policies;
2. A business plan for drug safety management, and the methods of financing;
3. Education and public campaign necessary for drug safety management;
4. Investigation, research, and development regarding drug safety management;
5. Other matters deemed necessary by the Minister of Food and Drug Safety for drug safety management.

(3) In order to implement a comprehensive plan, the Minister of Food and Drug Safety shall formulate an implementation plan for drug safety management (hereinafter referred to as “implementation plan") each year in consultation with the heads of the relevant central administrative agencies.

(4) Where the Minister of Food and Drug Safety formulates a comprehensive plan or an implementation plan, he or she shall notify it to the heads of the relevant central administrative agencies and the heads of local governments.

(5) Where necessary to formulate a comprehensive plan or an implementation plan, the Minister of Food and Drug Safety may request the provision of necessary data from the heads of the relevant central administrative agencies, the heads of local governments, or the heads of relevant institutions or organizations.

(6) Matters necessary to formulate and implement a comprehensive plan or an implementation plan shall be prescribed by Ordinance of the Prime Minister.

[Moved from Article 83-4; Previous Article 83-5 Moved to Article 83-6 *<Apr. 7, 2020>*]

Article 83-6 (Establishment and Operation of Integrated Drug Information System)

(1) The Minister of Food and Drug Safety shall establish and operate an integrated drug information system (hereinafter referred to as “integrated information system") to comprehensively manage the affairs necessary for safety management with respect to the clinical trials, permission by item, manufacturing, import, distribution, use, etc. of drugs, etc.

(2) The Minister of Food and Drug Safety may request the provision of information necessary to establish and operate an integrated information system (including sensitive information prescribed in Article 23 of the Personal Information Protection Act and personally identifiable information prescribed in Article 24 of

that Act; In such cases, the relevant information shall be protected in accordance with the Personal Information Protection Act) from the following institutions, organizations, or persons. In such cases, any institution, organization, or person upon receipt of such request shall comply with it, unless there is good cause:

1. The State or local governments;
2. Public institutions or public organizations;
3. Pharmacy founders; medical institution founders; manufacturers of drugs, etc., persons who have obtained permission by item, importers, or distributors; registered patentees; patentees, etc. of listed drugs; persons who have obtained permission for preferential distribution of items; persons who have obtained approval of clinical trial protocols; institutions conducting clinical trials; institutions conducting the analysis of clinical trial samples; institutions conducting non-clinical studies; and other persons prescribed by Ordinance of the Prime Minister who are engaged in handling drugs, etc.

(3) The Minister of Food and Drug Safety may entrust the affairs necessary for maintaining and managing an integrated information system to the Institute of Drug Safety and Risk Management. In such cases, the Minister of Food and Drug Safety may fully or partially subsidize the expenses incurred in maintaining and managing the integrated information system.

(4) Matters necessary for establishment and operation of an integrated information system, requests for the provision of information, entrustment, etc. under paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.

[Moved from Article 83-5 *<Apr. 7, 2020>]*

Article 83-7 (International Cooperation)

The Minister of Food and Drug Safety shall endeavor to promote international cooperation, such as concluding agreements with foreign governments, international organizations, etc. to ensure the safety and quality control of drugs and to facilitate their overseas expansion.

Article 84 (Delegation and Entrustment of Authority)

(1) The Minister of Health and Welfare may delegate part of his or her authority under this Act to the Commissioner of the Korea Disease Control and Prevention Agency or a Mayor/Do Governor, as prescribed by Presidential Decree. *<Amended on Aug. 11, 2020>*

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

(3) The Minister of Food and Drug Safety and the Mayors/Do Governor may delegate part of 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 delegate part of 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 under Article 67 or the Institute of Drug Safety and Risk Management with part of the pharmaceutical affairs under this Act, as prescribed by Presidential Decree.

Article 85 (Special Cases concerning Animal Drugs)

(1) Drugs, etc., the purpose of which is to be used exclusively for animals, among the matters 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 the "Minister of Health and Welfare" or "Minister of Food and Drug Safety" in the corresponding provisions of this Act shall be construed as the "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 or she shall consult with the Minister of Health and Welfare or the Minister of Food and Drug Safety. *<Amended on Mar. 23, 2013; Dec. 11, 2018>*

(2) The Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries may determine standards for use, such as animals for which such drugs are used, dose regimen, dose, and the period for prohibiting its use, regarding any of the following medications that are animal drugs, etc. used to treat or prevent animal diseases: *<Amended on Dec. 11, 2018>*

1. Medications designated as ones that may remain in an animal's body and cause any risk to human health;
2. Medications designated to be administered or used for the purpose of preventing infectious diseases in livestock or aquatic animals.

(3) A person who intends to use animal drugs, etc., the standards for use of which have been determined under paragraph (2), shall observe such standards: Provided, That where the person uses them in accordance with the treatment or prescription of a veterinarian or an aquatic organism disease inspector, he or she need not observe such standards. *<Amended on Dec. 11, 2018>*

(4) Notwithstanding Article 44, a person who has opened a veterinary hospital under the Veterinarians Act may distribute animal drugs to any person who cares for animals or may purchase animal drugs for the purpose of treating animals from any pharmacy founder under the proviso of Article 50 (2). In such cases, the person who has opened a veterinary hospital shall prepare and retain distribution 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 on Feb. 29, 2008; Mar. 23, 2013>*

(5) Notwithstanding Article 44, a person who has established an aquatic organism disease inspection center under the Aquatic Life Disease Control Act may distribute drugs for aquatic organisms to any aquaculture business entity. *<Amended on Jul. 21, 2011>*

(6) No person who has been permitted as a wholesaler of animal drugs under this Act shall distribute any of the following animal drugs, 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 issued by a veterinarian or an aquatic organism disease inspector: Provided, That the same shall not apply to where such drugs are distributed among a person who has opened a veterinary hospital, a person who has established an aquatic organism disease inspection center, a pharmacy founder, or a wholesaler of animal drugs: *<Newly Inserted on Feb. 1, 2012; Mar. 23, 2013>*

1. Animal drugs which are likely to cause any risk to human and animal health if misused or abused;
2. Animal drugs which require the expertise of a veterinarian or an aquatic organism disease inspector;
3. Animal drugs deemed likely to cause disorder in the dosage form and pharmacological actions.

(7) A pharmacy founder may distribute animal drug under the subparagraphs of paragraph (6) without a prescription issued by a veterinarian or an aquatic organism disease inspector: Provided, That the same shall not apply to any of the following animal drugs prescribed by the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries: *<Newly Inserted on Feb. 1, 2012; Mar. 23, 2013>*

1. An antibiotic substance medication for injection;
2. A biological medication for injection.

(8) Notwithstanding paragraphs (6) and (7), a person who distributes animal drugs pursuant to this Act may distribute animal drugs under the subparagraphs of paragraph (6) without a prescription issued by a veterinarian or an aquatic organism disease inspector, where he or she falls under any of the following cases. In such cases, the methods for distribution, the management of records, the scope of purchasers and 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 on Feb. 1, 2012; Mar. 23, 2013>*

1. Where such drugs are distributed to a livestock farmer or an aquaculture household on an island or remote area determined by the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries;
2. Where the use of animal drugs has been ordered by the Minister of Agriculture, Food and Rural Affairs, the Minister of Oceans and Fisheries, the Mayor/Do Governor, or the head of a Si/Gun/Gu for purposes of emergent control 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 distributes animal drugs, etc. pursuant to this Act shall comply with each of the following matters: *<Amended on Dec. 11, 2018>*

1. 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 of animal drugs, etc. and to

maintain order in distribution, such as prohibition against an act of collusion, designation of distribution places, and management of records;

2. Matters prescribed by Ordinance of the Ministry of Agriculture Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries to ensure the safe use of animal drugs, etc., such as preventing any abuse or misuse thereof.

(10) Where a person who distributes animal drugs, etc. pursuant to this Act distributes animal drugs, etc. for which Ordinance of the Ministry of Agriculture Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries provides that it is necessary to restrict the distribution due to the potential risk to humans or animals, he or she shall prepare and retain records on the transactions of such drugs, etc. *<Newly Inserted on Dec. 11, 2018>*

(11) A person who manages the affairs of a wholesaler of animal drugs pursuant to this Act shall receive education on safety assurance and quality management of animal drugs, as prescribed by Ordinance of the Ministry of Agriculture, Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries. *<Newly Inserted on Dec. 29, 2015; Dec. 11, 2018>*

(12) Notwithstanding Article 47 (1), a person who has been permitted as a wholesaler of animal drugs may distribute animal drugs to persons who care for animals or aquaculture business entities, as prescribed by Ordinance of the Ministry of Agriculture, Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries. *<Newly Inserted on Dec. 29, 2015; Dec. 11, 2018>*

Article 85-2 (Special Cases concerning Prophylactic Drugs and Therapeutic Drugs in Cases of National Emergencies)

(1) In order to properly address a pandemic of infectious diseases spread through bioterrorism prescribed in the Infectious Disease Control and Prevention Act and other infectious diseases or to address radiation emergencies prescribed in Article 2 (1) 7 of the Act on Physical Protection and Radiological Emergency, 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), an act of requiring a drug manufacturer to manufacture a drug for which permission by item or a notification by item has not been granted or filed;

2. Notwithstanding Article 42 (1), an act of requiring an importer to import a drug for which permission by item or a notification by item has not been granted or filed;

3. An act of requiring a drug manufacturer or an importer to manufacture or import a drug other than a drug for which permission by item or a notification by item has already been granted or filed, by specifying other dose regimen, dose, efficacy, effect, period of use, etc. inconsistent with the details permitted or notified.

(2) Where the Commissioner of the Korea Disease Control and Prevention Agency intends to extend the expiration date of a drug stored pursuant to Article 40 (1) of the Infectious Disease Control and Prevention Act, he or she may request the Minister of Food and Drug Safety to extend the expiration date. *<Amended*

on Aug. 11, 2020>

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

Article 85-3 (Special Cases concerning Ginseng Varieties under the Ginseng Industry Act)

(1) A ginseng varieties inspection agency specified in Article 17 (1) of the Ginseng Industry Act (hereafter in this Article, referred to as “ginseng varieties inspection agency”) may file an application for permission for drug manufacturing business pursuant to Article 31 (1) and may file an application for permission by item or file a notification by item under Article 31 (2) 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 filed a notification under Article 12 (1) of the Ginseng Industry Act (hereafter in this Article, referred to as “ginseng varieties manufacturer”) may distribute the red ginseng and white ginseng for which permission by item or a notification by item has been obtained or filed pursuant to paragraph (1), to any of the following persons, notwithstanding Article 44:

1. Herb druggists;
2. Drug wholesalers;
3. Pharmacy founders;
4. Medical institution founders handling herbal drugs.

(3) Articles 47, 69, 71, 94, 94-2, 95, 96, and 97 shall apply to any ginseng varieties manufacturer who distributes red ginseng and white ginseng pursuant to paragraph (2). In such cases, a ginseng varieties manufacturer shall be construed as a “manufacturer of drugs, etc.” and “person who obtained permission by item 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 85-4 (Special Cases concerning Obligation to Preserve and Retain Records)

Where any record to be preserved and retained under this Act is destroyed due to a natural disaster or other force majeure circumstances, the person obliged to preserve and retain such record shall be exempt from the relevant obligation prescribed in this Act.

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

(1) The Minister of Food and Drug Safety shall relieve injury from the side effects of drugs, and an organization consisting of drug manufacturers, persons who have obtained permission by item of a drug, or importers shall conduct research projects to facilitate the improvement of safety of drugs and the development of new drugs. *<Amended on Oct. 17, 2007; Mar. 18, 2014>*

(2) Drug manufacturers, persons who have obtained permission by item, or importers shall bear necessary expenses incurred in conducting projects prescribed in paragraph (1). *<Amended on 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 on Feb. 29, 2008; Jan. 18, 2010; 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 injury from the side effects of drugs. *<Newly Inserted on Mar. 18, 2014>*

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

(1) For the relief of injury prescribed in Article 86 (1), the Minister of Food and Drug Safety shall impose and collect charges for relief of injury from the side effects of drugs (hereinafter referred to as "charges") on and from drug manufacturers, persons who have obtained permission by item 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 amount of production or import of drugs classified as prescription drugs or over-the-counter drugs under this Act and additional charges imposed on drugs in need of relief of injury from the side effects as recognized by the Minister of Food and Drug Safety after deliberation by the Deliberative Committee, and such charges shall be prescribed by Presidential Decree to the extent not exceeding any of the following amounts:

1. Basic charges: 1/1,000 of the amount of production or import of drugs for the preceding year;
2. Additional charges: 25/100 of the amount paid for relief of injury from the relevant drugs of the preceding year: Provided, That no additional charge shall exceed 1/100 of the amount of production or import of the drugs for 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 injury, 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 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 shall organize and operate a financial operations committee for the imposition, collection, and operation of charges, as prescribed by Presidential Decree. *<Amended on Dec. 11, 2018>*

(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 entrusted with the imposition and collection of charges pursuant to the latter part of paragraph (1) shall demand such payment by specifying a period of at least 30 days. In such cases, a surcharge corresponding to a period

from the day following the payment deadline until the day before the date 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 demanded to make payment pursuant to paragraph (5) fails to pay a charge and a surcharge, they shall be collected in the same manner as delinquent national taxes are collected.

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

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

(1) If a person who uses a drug suffers from a disease or disability or dies due to the side effects of the drug, the president of the Institute of Drug Safety and Risk Management shall pay him or her any of the following benefits for relief of injury (hereinafter referred to as "benefits for relief of injury"):

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

(2) Notwithstanding paragraph (1), no benefit for relief of injury shall be paid in any of following cases:

1. Where the drugs are those determined by the Minister of Food and Drug Safety, which are used for cancer or specific diseases;
2. Where a disease, disability, or death due to the side effects of a drug has been caused by vaccinations prescribed in the Infectious Disease Control and Prevention Act;
3. Where a disease, disability, or death has been caused by intention or 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 valuables equivalent to the relief benefits have already been paid according to the Civil Act or other statutes and regulations on the grounds of the same disease, disability, or death;
6. Other cases prescribed by Ordinance of the Prime Minister.

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

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

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

(2) The president of the Institute of Drug Safety and Risk Management upon receipt of an application for benefits for relief of injury shall, without delay, investigate the details of side effects or injury, verify

whether the case corresponds to a medical accident, identify the causal relationship with drugs, investigate whether aftereffects of disability occur, and conduct an investigation, appraisal, etc. of the scope of indemnity for injury, restrictions on the payment of benefits for relief of injury, 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 investigation prescribed in paragraph (2) and an opinion on appraisal within 90 days from the date of receipt of a request for benefits for relief of injury: Provided, That where it is impracticable to conduct the investigation and appraisal due to new side effects, etc., the period may be extended by up to 30 days only one time.

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

(5) Where payment of benefits for relief of injury 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 inform 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 statutes and regulations, the president may guide him or her as to the method for obtaining such indemnity, as prescribed by Ordinance of the Prime Minister.

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

1. Article 86-3 (1) 1: Five years from the date the relevant medical treatment is provided;
2. Article 86-3 (1) 2 through 4: Five years from the date any disability or death occurs.

(7) Where the results of deliberation by the Deliberative Committee conflict with 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, the Minister of Food and Drug Safety and the president of the Institute of Drug Safety and Risk Management shall hold consultation for mediation, as prescribed by Presidential Decree.

(8) Where the president of the Institute of Drug Safety and Risk Management has an objection against the results of deliberation by the Deliberative Committee, he or 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 Advisory Committee thereabout and inform 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 injury within 30 days from the date the Minister of Food and Drug Safety makes a new decision.

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

Article 86-5 (Determination to Cease Payment of Benefits for Relief of Injury, and Collection of Unjust Enrichment)

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

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

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

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

Article 86-6 (Investigation of Injury from Side Effects)

(1) Where the president of the Institute of Drug Safety and Risk Management conducts an investigation and appraisal prescribed in Article 86-4 (2), he or she may request applicants, drug manufacturers, persons who have obtained permission by item, importers, distributors, pharmacy founders, medical institution founders, persons who distribute or handle drugs pursuant to this Act or other statutes, interested parties, or expert witnesses to appear and make a statement or to submit data, articles, etc. necessary for investigation.

(2) Where the president of the Institute of Drug Safety and Risk Management conducts an investigation and appraisal under Article 86-4 (2), he or she may request the medical personnel (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, acts of prescription and dispensation, etc. as at the time of prescription and dispensation.

(3) Where the president of the Institute of Drug Safety and Risk Management conducts an investigation and appraisal prescribed in Article 86-4 (2), he or she may have access to a drug manufacturer, person who has obtained permission by item, importer, or distributor of drugs causing side effects or a medical institution, pharmacy, etc. that prescribed or dispensed the relevant drug to investigate, peruse, or duplicate relevant documents or articles. In such cases, the investigator shall carry an identification indicating his or her authority and documents stating matters prescribed by Presidential Decree, such as the period and scope of an investigation, persons in charge of the investigation, and relevant statutes and regulations, and show it to relevant persons. *<Amended on Dec. 29, 2015>*

(4) For the investigation necessary to identify the causal relationship of side effects for a person who has filed an application for benefits for relief of injury, the president of the Institute of Drug Safety and Risk Management may request a government agency or a public 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 upon receipt of such request shall comply therewith, unless there is good cause.

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

(6) Except as provided in this Act, the Framework Act on Administrative Investigations shall apply to the procedures, methods, etc. for investigating, perusing, or duplicating documents or articles under paragraph (3). *<Newly Inserted on Dec. 29, 2015>*

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

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

Article 86-8 (Exemption from Public Dues)

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

Article 87 (Prohibition of Divulgence of Confidential Information)

(1) Neither pharmacist nor oriental medicine pharmacist shall divulge other person's confidential information which he or she has become aware of while dispensing and distributing drugs, except as provided in this Act or other statutes and regulations. *<Amended on Oct. 17, 2007>*

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

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

No person other than a manufacturer of drugs, etc., a person who has filed a notification of contract manufacturing and distribution business, a person who has obtained permission by item, an importer, or a distributer under this Act shall use similar names prescribed by Ordinance of the Prime Minister, such as pharmaceuticals and medicine, in his or her trade name.

Article 88 (Protection of Data Submitted)

(1) With respect to data submitted pursuant to Articles 31, 31-2, 32 through 34, 35-2, or 42, where 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 or she may disclose it. *<Amended on Jun. 7, 2011; Mar. 23, 2013>*

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

Article 89 (Succession to Status of Manufacturers)

(1) Where a manufacturer of drugs, etc., a person who has obtained permission by item of a drug, a person who has filed a notification of contract manufacturing and distribution business, a drug distributer (excluding herb druggists), a person who has obtained approval of a clinical trial protocol, or a person who has been designated as an inspection institution, etc. (hereafter in this Article and Article 89-2, referred to as "manufacturer, etc.") deceases or transfers the business or where a merger of corporate manufacturers, etc. occurs, a 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 the transferee, the corporation surviving the merger, or the corporation incorporated by the merger falls under any of the following cases: *<Amended on Oct. 17, 2007; Mar. 30, 2011; Jun. 7, 2011; Oct. 24, 2017>*

1. A manufacturer of drugs, etc., a person who has obtained permission by item of a drug, a person who has filed a notification of contract manufacturing and distribution business, and a person who has obtained approval of a clinical trial protocol: Where he or she falls under any of the subparagraphs of Article 31 (8);
2. A drug distributor: Where he or she falls under any of the subparagraphs of Article 46.

(2) Where a manufacturer of drugs, etc., a person who has obtained permission by item of a drug, a person who has filed a notification of contract manufacturing and distribution business, or an importer has transferred the business of drugs, etc. for which permission has been obtained or a notification has been filed regarding manufactured items or imported items pursuant to Article 31 (2) through (4) or 42 (1), another manufacturer, person who has obtained permission by item of a drug, person who has filed a notification of contract manufacturing and distribution business, or importer who takes over such business shall succeed to the status of the previous manufacturer, person who obtained permission by item of a drug, person who filed a notification of contract manufacturing and distribution business, or importer with respect to permission for and a notification of the relevant items. *<Amended on 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 notification 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 subparagraphs: 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 or she shall transfer such

status to another person within six months from the date when succession commenced: *<Amended on Mar. 23, 2013>*

1. A person who has succeeded to the status of a manufacturer of drugs, etc., a person who obtained permission by item of a drug, or a person who filed a notification of contract manufacturing and distributions 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, a transferee, a corporation surviving a merger, or a corporation incorporated by a merger shall succeed to the effects of administrative dispositions on the previous manufacturer, etc. and importer for one year from the date such disposition took place, and where the procedures for administrative dispositions are underway, the procedures for disposition of administrative sanctions may proceed for the transferee, the corporation surviving a merger, the corporation incorporated by a merger: Provided, That the same shall not apply where a new manufacturer, etc. (excluding the succession to the status by inheritance) or an importer succeeds to business and is not aware of such disposition or violation.

Article 90 (Monetary Awards)

A monetary award may be paid to any person who has reported or disclosed the fact of violating Article 23, 24 (1) and (2), 26 (1), 27 (1) and (3), or 50 (1) (including cases applied mutatis mutandis under Article 44-6 (1)) to any supervisory agency or any investigative agency, as prescribed by Presidential Decree. *<Amended on May 14, 2012; Apr. 7, 2020>*

Article 91 (Establishment of the 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 affairs of providing various information on the following drugs and supplying (including the affairs of dispensation and administration of drugs; hereinafter the same shall apply) such drugs: *<Amended on Dec. 2, 2016; Dec. 11, 2018>*

1. Orphan drugs;
2. National essential drugs;
3. Other drugs that need to be urgently introduced for public health or require support for the stable supply, among the drugs deemed necessary by the Minister of Food and Drug Safety.

(2) The Center shall be a corporation.

(3) The articles of association of the Center shall contain each of the following matters: *<Newly Inserted on Dec. 11, 2018>*

1. Objectives;
2. The name;
3. The location of the principal office;
4. Matters concerning assets;
5. Matters concerning the executive officers and employees;
6. The operation of the board of directors;
7. The scope, details, and execution of the business;
8. Accounting;
9. The methods of public announcement;
10. Amendment of the articles of association;
11. Other important matters concerning the operation of the Center.

(4) Where the Center intends to modify any matter stated in the articles of association, it shall obtain authorization from the Minister of Food and Drug Safety. *<Newly Inserted on Dec. 11, 2018>*

(5) The provisions governing an incorporated foundation in the Civil Act shall apply mutatis mutandis to the Center, except as provided in this Act. *<Amended on Dec. 11, 2018>*

(6) Matters necessary for the operation, etc. of the Center established under paragraph (1) shall be prescribed by Presidential Decree. *<Amended on Dec. 11, 2018>*

Article 92 (Projects of the Center)

(1) The Center shall conduct the following projects: *<Amended on Mar. 23, 2013; Dec. 2, 2016; Dec. 11, 2018>*

1. Projects for collecting various information regarding drugs prescribed in each subparagraph of Article 91 (1), and constructing a computer network;
2. Projects for supplying and stockpiling drugs prescribed in each subparagraph of Article 91 (1). In such cases, the president of the Center shall install a dispensary in the Center, designate a pharmacist from among the employees of the Center, and have such pharmacist be responsible for such project;
2-2. Projects for contract manufacturing and distribution of drugs prescribed in each subparagraph of Article 91 (1), pursuant to Article 31 (3) 4;
3. Projects related to the establishment of a stable supply base of, support for research and development of, and support for safe use of national essential drugs;
4. Other projects related to drugs prescribed in each subparagraph of Article 91 (1), which are deemed by the Minister of Food and Drug Safety.

(2) Where the Center implements projects specified in paragraph (1), the Minister of Food and Drug Safety may provide the Center with financial assistance, etc. *<Amended on Mar. 23, 2013>*

Article 92-2 (Legal Fiction as Public Officials for Purposes of Penalty Provisions)

Any of the following persons shall be deemed a public official for the purposes of Articles 127 and 129 through 132 of the Criminal Act: *<Amended on Jun. 12, 2018; Dec. 11, 2018>*

1. Drug epidemiological inspectors (in cases of an employee of the Institute of Drug Safety and Risk Management, the application of the penalty provisions of Article 127 of the Criminal Act shall be excluded);

2. The executive officers and employees of the Center;

3. The executive officers and employees of a corporation engaged in the affairs entrusted under Article 68-2 (2).

Article 92-3 (Re-Examination of Regulation)

The Minister of Food and Drug Safety shall examine the appropriateness of permission for preferential distribution of items and the amount of administrative fines referred to in Article 97-2 every three years, counting from January 1, 2015 (referring to the period that ends on the day before January 1 of every third year) and shall take measures, such as making improvements.

CHAPTER IX PENALTY PROVISIONS

Article 93 (Penalty Provisions)

(1) Any of the following persons shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 50 million won: *<Amended on Oct. 17, 2007; Jan. 28, 2015; Dec. 29, 2015; Oct. 24, 2017; Dec. 11, 2018; Apr. 7, 2020>*

1. A person who lent his or her qualification certificate for a tourism worker to any other person, in violation of Article 6 (3).

1-2. A person who has lent a license or arranges for a license to be lent, in violation of Article 6 (4);

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 permission, to file a notification, to obtain permission for modification, or to file a notification of modification, in violation of Article 31 (1) through (4) or (9);

4-2. A person who has obtained permission or permission for modification under Article 31 (1) through (4) or (9) by false or other fraudulent means, or has made a report or report of change;

4-3. A person who has registered or registered a drug substance under Article 31-2 (1) and (3) (including cases applied mutatis mutandis in Article 42 (5)) by false or other fraudulent means;

5. A person who fails to obtain permission, to file a notification, to obtain permission for modification, or to file a notification of modification, in violation of Article 42 (1);

5-2. A person who has obtained permission or permission for change under Article 42 (1), or has made a report or report of change by false or other fraudulent means;

6. A person who violates Article 43;

6-2. A person who has obtained permission under Article 43 (1) by false or other illegal means;

7. A person who violates Article 44 (1);

8. A person who distributes drugs without obtaining permission under Article 44 (2) 2;

8-2. A person who has registered under Article 44-2 (1) or registered for modification under paragraph (3) of the same Article by fraudulent or other fraudulent means;

8-3. A person who has obtained permission or permission for change under Article 45 (1), or has made a report or report of change by false or other fraudulent means;

9. A person who violates Article 53 (1);

10. A person who violates Article 61 (including cases applied mutatis mutandis under Article 66): Provided, That the same shall not apply to those who violate Article 56 (2) (including cases applied mutatis mutandis under Article 44-6 (1)) or Article 65 (2);

11. A person who falsely prepares and issues a clinical trial report, an analysis report of clinical trial samples, or a non-clinical study report referred to in Article 34-2 (3) 5 or 34-3 (3).

(2) In cases falling under paragraph (1), imprisonment with labor and a fine may be imposed concurrently.

Article 94 (Penalty Provisions)

(1) Any of the following persons shall be punished by imprisonment with 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 or her: *<Amended on Oct. 17, 2007; Jun. 7, 2011; Feb. 1, 2012; May 14, 2012; Jan. 28, 2015; Dec. 2, 2016; Oct. 24, 2017; Dec. 11, 2018; Apr. 7, 2020>*

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 clause of Article 34 (1), Article 34 (3) 1 or 2, or paragraph (4) of that Article, or a person who violates an order prescribed in paragraph (6) of that Article;

3-2; A person who obtains approval of a protocol of a clinical trial under Article 34 (1) or approval for modification of such protocol by fraud or other improper means;

3-3. A person who conducts clinical trials without obtaining designation, in violation of Article 34-2 (1);

3-4. A person who conducts clinical trials without obtaining designation of modification, in violation of the main clause of Article 34-2 (2);

3-5. A person who violates Article 34-2 (3) 1 or 2;

4. A person who violates Article 37 (3) (including cases applied mutatis mutandis under Article 42 (5));

4-2. A person who fails to recall drugs or to take necessary measures for recall, in violation of the former part of Article 39 (1) (including cases applied mutatis mutandis under Article 44-6 (1));

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 that Article. In such cases, any economic benefit, etc. acquired shall be confiscated; and where it is impossible to confiscate such economy benefit, etc., a

value equivalent thereto shall be collected;

6. Deleted; *<Dec. 29, 2015>*

7. A person who distributes, stores, or displays drugs, in violation of Article 49;

8. A person who violates Article 50 (1) (including cases applied mutatis mutandis under Article 44-6 (1));

9. A person who distributes, manufactures, imports, stores, or displays drugs, in violation of Article 62 (including case applied 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 business without good cause, in violation of Article 70 (2);

11. A person who violates an order under Articles 71 (1) and (2) (including cases applied mutatis mutandis under Article 44-6 (1)) and 72 (1) and (2) (including cases applied mutatis mutandis under Article 44-5 (1)), or refuses, obstructs, or evades the recall and destruction of articles, which are conducted by relevant public officials pursuant to Article 71 (3) (including cases applied mutatis mutandis under Article 44-6 (1)), and other necessary dispositions;

12. A person who violates Article 87 or 88 (2).

(2) In cases falling under paragraph (1), imprisonment with labor and a fine may be imposed concurrently.

Article 94-2 Deleted. *<Dec. 2, 2016>*

Article 95 (Penalty Provisions)

(1) Any of the following persons shall be punished by imprisonment with labor for not more than one year or by a fine not exceeding 10 million won: *<Amended on Jul. 27, 2007; Oct. 17, 2007; Nov. 14, 2007; Feb. 27, 2010; Mar. 12, 2011; Feb. 12, 2012; Jan. 14, 2012; Jul. 28, 2013; Feb. 29, 2015; Jan. 11, 2014; Feb. 13, 2014; May 14, 2014>*

1. A person who fails to file for registration of establishment in violation of the former part of Article 20 (2);

1-2. A person who has registered the establishment or modification thereof under Article 20 (2) by fraud or other improper means;

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 good 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. A person who fails to obtain insurance or to compensate test subjects in compliance with the procedures, etc. for compensation explained to them in advance, in violation of Article 34 (3) 5;

6-3. A person who fails to evaluate, record, retain, or report the safety information of drugs, etc. for clinical trials or who evaluates, records, retains, or reports such data falsely, in violation of Article 34 (3) 6;

6-4. A person who fails to prepare, retain, or report records on clinical trials or who prepares, retains, or reports such records falsely, in violation of Article 34-2 (3) 5 (excluding any violation prescribed in Article 93 (1) 11);

7. A person who fails to perform the affairs of safety management, in violation of Article 36 (including cases applied mutatis mutandis under Article 42 (5)), 37 (2) (including cases applied mutatis mutandis under Article 42 (5)) or 37-3 (1) (including cases applied mutatis mutandis under Article 42 (5));

7-2. A person who fails to comply with the duty to manage the manufacturing or production of drugs, etc., in violation of Article 37 (1) or 38 (1);

7-3. A person who fails to report a plan for recall or files a false report, in violation of the latter part of Article 39 (1);

8. A person who violates Article 47 (1) (excluding Article 47 (1) 3 (b) and including cases applied mutatis mutandis under Article 44-6 (1)) or (4), or 85 (9);

8-2. A person who removes the seal on a container or package of drugs affixed and distributes them, in violation of the main clause of Article 48;

9. A person who distributes prescription drugs, in violation of Article 50 (2);

9-2. A person who is registered under Article 50-2 (4), by fraud or other improper means;

9-3. A person who files an application for prohibition of distribution or permission for preferential distribution of items under Article 50-5, by fraud or other improper means;

10. A person who violates Article 60 (including cases applicable mutatis mutandis pursuant to Article 66), 64 (1), or 68;

10-2. A person who arranges or advertises the distribution of drugs, in violation of Article 61-2 (1);

10-3. A person who reports the details of agreement prescribed in Article 69-3, by fraud or other improper means;

11. A person who distributes animal drugs without a prescription, in violation of Article 85 (6) and (7);

12. A person who receives benefits for relief of injury by fraud or other improper means prescribed in Article 86-5 (2) 1.

(2) Imprisonment with labor and a fine under paragraph (1) may be imposed concurrently.

(3) Where a person is sentenced to punishment for committing a crime prescribed in paragraph (1) 7-2 and commits a crime prescribed in that subparagraph again within three years from the date his or her sentence becomes final and conclusive, the punishment shall be aggravated by up to 1/2 of the corresponding punishment. *<Newly Inserted on Dec. 11, 2018>*

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 a person who violates Article 30 (2) may be prosecuted only where a criminal complaint is filed against him or her: *<Amended on Oct. 17, 2007; Jun. 7, 2011; Feb. 1, 2012; May 14, 2012; Mar. 18, 2014; Jan. 28, 2015; Dec. 29, 2015; Dec. 2, 2016; Oct. 24, 2017; Dec. 11, 2018; Apr. 7, 2020>*

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 Article 37-3 (2) or 47 (1) 3 (b);
3-2. A person who releases any drug into the market without placing an identification mark thereon or without registering an identification mark, in violation of Article 38-2 (1) (including cases applied mutatis mutandis under Article 42 (5));
3-3. A person who releases any drug into the market without registering a modification, in violation of Article 38-2 (2) (including cases applied 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 evidentiary data, in violation of Article 47-2 (1);
3-5. A person who prepares a false expense report under Article 47-2 (1);
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 evidentiary data;
4. A person who violates Article 56 (1), 57, 58, 63 (including cases applied mutatis mutandis under Article 66), 65 (1), or 65-2, or subparagraphs 1 through 3 of Article 65-3;
5. A person who refuses, obstructs, or evades any investigation, inspection, inquiry, collection, etc. by drug epidemiological inspectors or relevant public officials prescribed in Article 68-12 (3) or 69 (1) (including cases applied mutatis mutandis in Article 44-6 (1));
6. A person who violates an order for report, announcement, inspection, improvement, replacement, etc. prescribed in Articles 69 (1) (including cases applied mutatis mutandis under Article 44-6 (1)), 72 (3) and (4), 73, 74, and 75;
7. A person who refuses, obstructs, or evades investigation, perusal, or duplication prescribed in Article 86-6 (3) without good cause.

Article 97 (Joint Penalty Provisions)

Where the representative of a corporation or an agent or employee of, or any other person employed by, the corporation or an individual commits any violations described in Article 93, 94, 94-2, 95, 95-2, or 96 in connection with the business affairs of the corporation or individual, the corporation or individual shall, in addition to punishing the violators accordingly, be punished by a fine prescribed in the relevant Article: Provided, That this shall not apply where such corporation or individual has not been negligent in giving

due attention and supervision concerning the relevant business affairs to prevent such violation.

Article 97-2 (Administrative Fines)

(1) A person who fails to report the details of agreement under Article 69-3 without good cause shall be subject to an administrative fine of not more than 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 subject to an administrative fine of not more than one million won: *<Amended on Oct. 17, 2007; Jun. 7, 2011; May 14, 2012; Jul. 30, 2013; Mar. 18, 2014; Jan. 28, 2015; Dec. 2, 2016; Oct. 24, 2017; Dec. 11, 2018; Jan. 15, 2019; Apr. 7, 2020>*

1. Deleted; *<Apr. 7, 2020>*

2. Deleted; *<Apr. 7, 2020>*

2-2. A person who fails to file for registration of modification, in violation of the latter part of Article 20 (2);

2-3. A person who uses the word "pharmacy" or similar names, in violation of Article 20 (6);

3. A person who fails to observe matters necessary for the management of a pharmacy even after receiving a corrective order referred to in Article 69-4, 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 file a notification of business closure, in violation of Article 22 or Article 40 (1) (including cases applied mutatis mutandis in Article 42 (5));

4-2. A person who fails to receive education, in violation of Article 37-2 (including cases applied mutatis mutandis in Article 42 (5));

4-3. A person who fails to receive education, in violation of Article 37-4 (including cases applied mutatis mutandis in Article 42 (5));

4-4. A person who fails to file a report on modification in violation of the proviso of Article 34 (1) or the proviso of Article 34-2 (2) or who publicly announces the recruitment of subjects of a clinical trial in violation of Article 34 (3) 3;

4-5. A person who fails to have persons engaged in clinical trials receive education, in violation of Article 34-4 (1) and (2);

5. A person who fails to file a report on production performance, import performance, etc. of drugs, etc., in violation of Article 38 (2) (including cases applied mutatis mutandis in Article 42 (5));

5-2. A person who fails to implement measures necessary for drugs, etc. in violation of Article 40 (2) (including cases applied mutatis mutandis in Article 42 (5));

6. Deleted; *<Feb. 1, 2012>*

6-2. A person who fails to file a notification of the manufacturing, etc. of pharmacy medication or dispensary medication, in violation of Article 41 (1);

6-3. A person who fails to file a notification of business closure, suspension, or resumption, in violation of the main clause 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 the matters to be observed by distributors of safe and readily available drugs, in violation of Article 44-4;

7-2. A person who fails to submit the details of supply of drugs, in violation of Article 47-3 (2) (including cases applied mutatis mutandis under Article 44-6 (2));

7-3. A person who fails to indicate the price of a drug on the container or package of a drug even after receiving a corrective order referred to in Article 69-4, in violation of Article 56 (2) (including cases applied mutatis mutandis under Article 44-6 (1)) or 65 (2);

7-4. A person who fails to comply with a request for submission of data without good cause, in violation of Article 61-2 (2);

7-5. A person who fails to file a report on an adverse event, in violation of Article 68-8;

7-6. A person who uses the name “Institute of Drug Safety and Risk Management” or similar names, in violation of Article 68-10;

7-7. A person who fails to appear without good cause after receiving a request to appear under Article 86-6 (1) (excluding expert witnesses);

7-8. A person who fails to submit data, articles, etc. prescribed in Article 86-6 (1) without good cause after receiving a request to submit such data, articles, etc. (excluding expert witnesses);

7-9. A person who fails to comply with a request to make a statement prescribed in Article 86-6 (2) without good cause after receiving such request;

8. Deleted; *<Feb. 1, 2012>*

9. A person who fails to renew a license, a permit, or a certificate of registration, in violation of Article 80;

10. A person who fails to observe the standards for use of drugs, etc. for animals, in violation of Article 85 (3);

10-2. A person who fails to prepare and retain records on the transactions of drugs, etc. for animals or who falsely prepares or retains such records, in violation of Article 85 (10);

11. A person who uses similar names prescribed by Ordinance of the Prime Minister, such as pharmaceuticals 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, the Mayor/Do Governor, or the heads of Sis/Guns/Gus, as prescribed by Presidential Decree. *<Amended on Feb. 29, 2008; Jan. 18, 2010; Jun. 7, 2011; Mar. 23, 2013>*

(3) Deleted. <*Jun. 7, 2011*>

(4) Deleted. <*Jun. 7, 2011*>

(5) Deleted. <*Jun. 7, 2011*>

ADDENDA <*Act No. 8365, Apr. 11, 2007*>

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

Article 3 (Applicability to Disposition of Imposition of Penalty Surcharges)

The amended provisions of Article 81 (4) shall begin to apply to persons who receive any disposition of penalty surcharges on or after July 4, 2007, the enforcement date of the Pharmaceutical Affairs Act (Act No. 8201).

Article 4 (Transitional Measures concerning Drugs for Family Planning)

The amended provisions of Articles 44, 50 and 68 (4) shall not apply to items determined by the Minister of Health and Welfare, from among drugs for family planning. Notwithstanding the amended provisions of Articles 44 and 50, those designated by the Minister of Health and Welfare may be allowed to present or distribute only items designated by the Minister of Health and Welfare, as prescribed by the Ordinance of the Ministry of Health and Welfare, regarding the presentation and distribution of drugs in the trains, airplanes, or other places designated by the Minister of Health and Welfare.

Article 5 (Transitional Measures concerning Druggists)

Druggists who have obtained permission pursuant to the previous statutes and regulations (referring to drug dealers under the previous statutes and regulations) as of January 13, 1971, the enforcement date of the Pharmaceutical Affairs Act (Act No. 2279), and drug sellers shall be governed by the previous statutes and regulations.

Article 6 (Transitional Measures concerning Herb Druggists)

Those who have been granted permission for herb dealers as of January 13, 1971, the enforcement date of the 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)

As for those who have left the permitted area due to war or other acts of God from among the herb dealers as of January 13, 1971, the enforcement date of the Pharmaceutical Affairs Act (Act No. 2279), and those who have left the permitted area before March 3, 1967, the enforcement date of the Pharmaceutical Affairs Act (Act No. 1910), their place of residence may be deemed a permitted area only if they obtain permission from the Seoul Special Metropolitan City Mayor, Busan Metropolitan

City Mayor, or a Do Governor who has the jurisdiction of the place of residence concerned.

Article 8 (Transitional Measures concerning Dispensation by Oriental Medical Doctors and Veterinarians)

Where an oriental medical doctor directly dispenses herbal drugs and herbal medications which he or she uses for treatment, or a veterinarian directly dispenses animal drugs which he or she uses for treatment, he or she may dispense them, notwithstanding the amended provisions of Article 23 (1) and (2).

Article 9 (Transitional Measures concerning Dispensation of Herbal Drugs by Pharmacists)

Any of the following persons may dispense herbal drugs pursuant to the amended provisions of Article 23 (6), notwithstanding the amended provisions of Article 23 (1):

1. A person who has a pharmacist license or who has not obtained a pharmacist license after graduating from a college majoring in pharmacology as at the time the Pharmaceutical Affairs Act (Act No. 4731) entered into force, who has passed the herbal drug dispensation examination prescribed by Presidential Decree within two years from the enforcement date of that Act: Provided, That the herbal drug dispensation examination shall be taken after obtaining a pharmacist license;

2. A person who attended a college majoring in pharmacology as at the time the Pharmaceutical Affairs Act (Act No. 4731) entered into force, who completed the herbal drug related course prescribed by the Ordinance of the Ministry of Health and Welfare and has passed the herbal drug dispensation examination prescribed by Presidential Decree within two years after the graduation: Provided, That the herbal drug dispensation examination shall be taken after obtaining a pharmacist license.

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

Druggists in operation as of July 1, 2000, the enforcement date of the Pharmaceutical Affairs Act (Act No. 6153), shall not distribute prescription drugs in an area other than the area designated by the Minister of Health and Welfare as an area where there is no medical institution or pharmacy pursuant to the amended provisions of Article 23 (5).

Article 11 (Transitional Measures concerning Substitute Dispensation)

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 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 drug related courses stipulated in Article 3-2 of the amended Enforcement Decree of the Pharmaceutical Affairs Act (Act No. 14319) as conferred under Article 3-2 (2) of the Pharmaceutical Affairs Act (Act No. 7376) in a college and have succeeded in the national examination for an oriental medicine pharmacist license from among those falling under any of the following subparagraphs shall be granted an oriental medicine pharmacist license notwithstanding the amended provisions of Article 4 (2):

1. Those who have been attending a college majoring in pharmacology (limited to a department other than the herbal 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;

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 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 provisions of Article 4.

Article 15 (Transitional Measures concerning Qualification for Applying for National Examinations for Pharmacist License or Oriental Medicine Pharmacist License)

Those who have the qualification for applying for the national examinations for a pharmacist license or an oriental medicine pharmacist license shall be deemed to have the qualification for application pursuant to this Act.

Article 16 (Transitional Measures concerning the Korean Pharmaceutical Association)

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 license or oriental medicine pharmacist license pursuant to the previous provisions as 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)

Acts by administrative agencies or acts towards administrative agencies pursuant to the previous provisions as 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 provisions shall govern.

Article 21 Omitted.

Article 22 (Relationship to Other Statutes and Regulations)

Where the previous Pharmaceutical Affairs Act or a provision thereof is cited by other statutes and regulations 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 to Confirmation of Suspect Matters of Prescription) The amended provisions of Article 26 (2) concerning confirmation of suspect matters of a prescription shall begin to apply to prescriptions written on or after the date 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 Public Notice, Disposition, Order, and On-Going Acts) Public notice, dispositions, orders, and other acts of administrative agencies or various applications, notifications, and other acts to administrative agencies under the previous Pharmaceutical Affairs Act as at the time this Act enters into force shall be deemed acts of administrative agencies or acts to administrative agencies under this Act corresponding thereto.

(3) (Transitional Measures concerning Penalty Provisions) Acts that violated the previous Pharmaceutical Affairs Act as at the time this Act enters into force shall be governed by the previous Pharmaceutical Affairs Act in applying the provisions of penalty or administrative fines.

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

Article 1 (Enforcement Date)

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

Articles 2 through 5 Omitted.

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

Article 1 (Enforcement Date)

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

Articles 2 through 6 Omitted.

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

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation: Provided, That ... <*omitted*> ... *the amendments to the Acts, which were promulgated before this Act enters into force but whose enforcement dates have not yet arrived, among the Acts amended by Article 6 of the Addenda, shall enter into force on the enforcement dates of the respective Acts.*

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 with Drugs and Medical Devices Combined)

The amended provisions of Article 31 (7) (including cases applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)) shall begin to apply to applications for permission by item or notifications by item filed on or after the date this Act enters into force.

Article 3 (Applicability to Submission of Test Results)

The amended provisions of Article 31 (10) 1 and 2 (including cases applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)) shall begin to apply to applications for permission by item or notifications by item filed on or after the date this Act enters into force.

Article 4 (Transitional Measures concerning Drug Substances Subject to Notification)

A drug substance, a notification of 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 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 been permitted as a drug wholesaler pursuant to the previous provisions as at the time this Act enters into force shall be deemed to obtain permission pursuant to the amended provisions of Article 45: Provided, That he or she shall have facilities prescribed in the amended provisions of Article 45 within two years from the enforcement date of this Act.

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, and 98 (1) 7-4 and 7-5 shall enter into force six months after the date of its promulgation: Provided, That Article 2 of these 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 of Clinical Trials)

The amended provisions of Article 34 (1) shall begin to apply to persons who apply for approval of a protocol for a clinical trial or bioequivalence test using drugs, etc. after this Act enters into force.

Article 4 (Applicability to Labeling of Containers)

The amended provisions of Article 65 (1) 4 shall begin to apply to quasi-drugs manufactured or imported after this Act enters into force.

Article 5 (Applicability to Fees)

The amended provisions of Article 82 shall begin to apply to applications for approval of a protocol for a clinical trial or bioequivalence test and designation of an institution conducting non-clinical studies, etc. after this Act enters into force.

Article 6 (Transitional Measures concerning Designation of Institutions Conducting Clinical Trials)

(1) An institution conducting clinical trials 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 an institution conducting clinical trials 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 the 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 the Mayor/Do Governor pursuant to the amended provisions of Article 73 (1).

Article 7 (Transitional Measures concerning the Korean Pharmacopoeia)

The Korean Pharmacopoeia publicly announced as at the time this Act enters into force shall be deemed publicly announced as the Pharmacopoeia of the Republic of Korea under the amended provisions of Article 51.

Article 8 (Transitional Measures concerning State-Verified Drugs)

A drug verified 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 approval of 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 to Other Statutes and Regulations)

Where the provisions of the previous Pharmaceutical Affairs Act are cited by other statutes and regulations 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 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 Pharmaceutical Affairs Act (Act No. 10788) shall enter into force 18 months after the date of its promulgation.

Article 2 (Transitional Measures concerning Labeling on Containers, Packages, and Package Inserts of Quasi-Drugs)

Labeling on containers, packages, or package inserts of quasi-drugs (including marks) under 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 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 Pharmaceutical Affairs Act (Act No. 11251) shall enter into force on August 2, 2013.

Article 2 (Special Cases concerning Period of Validity of Permission by Item or Notification by Item)

Notwithstanding the amended provisions of Article 31-5 (1) (including cases applied mutatis mutandis under the amended provisions of the former part of Article 42 (4)), the period of validity of a drug for which permission by item or a notification by item was granted or filed before January 1, 2013 and a drug the re-review period of which expired before January 1, 2013 shall be extended to the date determined and publicly notified by the Minister of Food and Drug Safety within the scope from January 1, 2018 to December 31, 2023. <*Amended on 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) The amendments to the Acts, which were promulgated before this Act enters into force but whose enforcement dates have not yet arrived, among the Acts amended by Article 6 of the Addenda, shall enter into force on the enforcement dates of the respective Acts; but the amended provisions of Article 47 (1) of the Pharmaceutical Affairs Act under paragraph (477) of that Article of the Addenda and the amended provisions of Article 18 (1) of the Medical Devices Act under paragraph (481) of that Article of the Addenda shall enter into force on the date prescribed by Presidential Decree regarding the relevant statutes within the scope of one year after this Act enters into force.

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 to Suspension of Business)

The amended provisions of Article 76 (1) shall also apply 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 its promulgation; the amended provisions of Articles 2, 24 (4) and 98 (1) 3-2 three months after the date of its promulgation; the amended provisions of Articles 37-4, 42 (4) and 98 (1) 4-3 six months after the date of its promulgation.

Article 2 (Preparation for Imposition and Collection 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 to Relief of Injury)

The relief of injury from the side effects of drugs shall begin to apply to any injury from side effects that occurs after this Act enters into force.

Article 4 (Phased Application of Extent of Payment of Benefits for Relief of Injury)

The payment of benefits for relief of injury 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)

Notwithstanding the amended provisions of Article 5, the previous provisions shall apply to persons for whom the declaration of incompetency or quasi-incompetency remains effective pursuant to Article 2 of Addenda to the Civil Act (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, and 93 (1), Article 94 (1) with the exception of its subparagraphs, subparagraphs 3 (limited to the parts related to Article 34 (3) and (4)), 3-2 and 3-3 of that paragraph, and Article 95 (1) with the exception of its subparagraphs shall enter into force on the date of its promulgation; and the amended provisions of Article 33 shall enter into force six months after the date of its promulgation.

Article 2 (Applicability to Approval of Protocols of Clinical Trials)

The amended provisions of Article 34 (1) shall begin to apply to applications for approval of modification of protocols of clinical trials, etc. filed after this Act enters into force.

Article 3 (Applicability to Extension of Expiration Date 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 Notification of Import Business)

A person intending to conduct business of importing drugs, etc. after this Act enters into force, who is an importer of drugs, etc. and has obtained permission by item or has filed a notification by item of drugs, etc. pursuant to the previous provisions before this Act enters into force or who is an importer falling under Article 42 (2), shall file a notification of import business pursuant to the amended provisions of Article 42 within one year after this Act enters into force.

ADDENDA <*Act No. 13219, Mar. 13, 2015*>

Article 1 (Enforcement Date)

This Act shall enter into force on March 15, 2015: Provided, That the amended provisions of Article 42 (5) of the Pharmaceutical Affairs (Act No. 13114) shall enter into force on September 29, 2015.

Article 2 (Applicability to Application for Prohibition of Distribution)

The amended provisions of Article 50-5 (1) (including cases applied pursuant to the amended provisions of Article 42 (4)) shall begin to apply where a person who files an application for permission

by item or permission for modification of a drug after this Act enters into force is informed pursuant to the amended provisions of Article 50-4 (1) or (2) (including cases applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)).

Article 3 (Applicability to Application for Permission for Preferential Distribution of Items)

The amended provisions of the subparagraphs of Article 50-7 (2) (including cases applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)) shall also apply to the persons who filed a petition for a trial pursuant to the amended provisions of the subparagraphs of Article 50-7 (2) regarding the registered patent before this Act enters into force (hereafter in this Article, referred to 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 to Permission for Preferential Distribution of Items)

The amended provisions of Article 50-8 (1) 1 (including cases applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)) shall begin to apply to persons who file an application for permission by item or permission for modification of a drug required to be informed pursuant to the amended provisions of Article 50-4 (including cases applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)) after this Act enters into force.

Article 5 (Applicability to Prohibition of Distribution of Same Drugs)

The amended provisions of Article 50-9 (1) (including cases applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)) shall begin to apply to drugs for which an application for permission by item is filed or drugs required to be informed pursuant to Article 50-4 (2) after this Act enters into force.

Article 6 (Applicability to Report on Details of Agreement)

The amended provisions of Article 69 (3) (including cases applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)) shall begin to apply where agreement is reached pursuant to the amended provisions of the subparagraphs of Article 69-3 after this Act enters into force.

Article 7 (Applicability to Fees)

The amended provisions of Article 82 (2) 2-2 shall begin to apply to applications for registration or modification of the registered matters after this Act enters into force.

Article 8 (Applicability to Registration Fees)

The amended provisions 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 of Drug Patents)

(1) Where an application for registration in the drug patent list was filed pursuant to the previous Article 31-3 (1) before this Act enters into force, the previous provisions shall apply to the subject matters and standard of registration, notwithstanding the amended provisions of Article 50-2 (4) (including case applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)).

(2) The drug patent registered in the drug patent list pursuant to the previous 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 provisions of Article 50-2 (including cases applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)).

Article 10 (Transitional Measures concerning Modification of Registered Matters)

The previous Article 31-3 (3) shall apply to an application for registration of modification where the patent information registered in the patent list was modified before this Act enters into force, notwithstanding the amended provisions of Article 50-3 (2) (including cases applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)).

Article 11 (Transitional Measures concerning Modification or Deletion of Registered Matters by Authority)

The previous Article 31-3 (5) shall apply to the modification or deletion by authority of the patent information of a drug registered in the patent list pursuant to the previous Article 31-3 (2) before this Act enters into force, notwithstanding the amended provisions of Article 50-3 (4) 1 and 3 (including cases applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)).

Article 12 (Transitional Measures concerning Informing of Application for Permission by Item)

The previous Article 31-4 shall apply to the person who filed an application for permission by item of a drug, based on the safety and effectiveness information of the listed drug pursuant to Article 31 (2) or (3) before this Act enters into forces, notwithstanding the amended provisions of Article 50-4 (1) (including case applied mutatis mutandis pursuant to the amended provisions of Article 42 (4)): Provided, That where the grounds falling under the amended provisions of Article 50-4 (1) 2 through 4 cease to exist after this Act enters into force, the amended provisions of paragraph (2) of that Article shall apply thereto.

Article 13 (Transitional Measures concerning Administrative Dispositions)

The previous provision shall apply to the administrative dispositions against the violations before this Act enters into force, notwithstanding the amended provisions 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. 13598, Dec. 22, 2015>*

Article 1 (Enforcement Date)

This Act shall enter into force two years after the date of its promulgation.

Article 2 (Transitional Measures concerning Payment of Price for Existing Drug Transactions)

Where the date of drug transaction is earlier than the date this Act enters into force, the payment shall be deemed made pursuant to the amended provisions of Article 47 (5) through (7) if the relevant purchase price is paid within one year from the date this Act enters into force.

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 previous 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: Provided, That--- *<Omitted>---Article 4 of the Addenda shall enter into force on August 4, 2016.*

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 of Expense Report)

The amended provisions of Article 47-2 shall begin to apply to the next fiscal year of the fiscal year which the enforcement date of the same amended provisions belongs to.

Article 3 (Applicability to Modification of Labeling of Containers of Drugs or Quasi-Drugs)

The amended provisions of Articles 56 (1) and 65 (1) shall begin to apply to drugs, etc. manufactured or imported after the same amended provisions enter into force.

Article 4 (Applicability to Products Manufactured, Processed, or Imported Using Similar Names such as Pharmaceuticals and Medicine)

The amended provisions of Article 87-2 shall begin to apply to products manufactured, processed, or imported after the same amended provisions enter into force.

Article 5 (Transitional Measures concerning Modification of Labeling of Containers of Drugs or Quasi-Drugs)

Labeling on the containers, etc. of drugs, etc. under the previous provision as at the time this Act enters into force may be used as the labeling of the relevant item until one year after the same amended provisions enter 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 Pharmaceuticals and Medicine)

Products manufactured, processed, or imported by using similar names prescribed by Ordinance of the Prime Minister such as pharmaceuticals and medicine as at the time this Act enters into force may be distributed or be displayed or transported for distribution purposes, or used for business until one year after the same amended provisions enter into force, notwithstanding the amended provisions of Article 87-2.

Article 7 (Transitional Measures concerning Application of Prescription of Disposition of Suspension of Qualifications)

No disposition of suspension of qualifications 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 qualifications 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 Penalty Provisions)

The previous provisions shall apply to the application of penalty provision against acts before this Act enters into force.

Article 9 (Transitional Measures concerning Administrative Fines)

The previous provisions shall apply to the application of administrative fines against acts before this Act enters into force.

ADDENDUM *<Act No. 14560, Feb. 8, 2017>*

This Act shall enter into force three years after the date of its promulgation.

ADDENDA *<Act No. 14839, Jul. 26, 2017>*

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation: Provided, That the amendments to the Acts, which were promulgated before this Act enters into force but whose enforcement dates have not yet arrived, among the Acts amended by Article 5 of these Addenda, shall enter into force on the enforcement dates of the respective Acts.

Articles 2 through 6 Omitted.

ADDENDA *<Act No. 14926, Oct. 24, 2017>*

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 31 (8) 2 and 42 (4) 2 shall enter into force on the date of its promulgation; and the amended provisions of Articles 11 (5), 12 (5), and 68 (6) and (7); subparagraph 4 of Article 69-4; and Articles 79 (2) 3, 79-2, and 98 (1) 3 and 7-3 shall enter into force six months after the date of its promulgation.

Article 2 (Applicability to Matters to Be Observed by Persons Intending to Conduct Clinical Trials)

The amended provisions of the main clause of Article 34 (3) 1 (applicable only to the provisions requiring clinical trials to be conducted at an institution conducting the analysis of clinical trial samples) shall begin to apply to cases of applying for approval of clinical trial protocols under the amended provisions of the main clause of Article 34 (1) after this Act enters into force.

Article 3 (Applicability to Public Announcement on Recruitment of Subjects of Clinical Trials)

The amended provisions of Article 34 (3) 3 shall begin to apply to persons who publicly announces the recruitment of subjects of clinical trials in order to conduct clinical trials after this Act enters into force.

Article 4 (Applicability to Prohibition on Advertising Prescription Drugs)

The amended provisions of Article 68 (6) shall apply to advertisements of drugs conducted after the same amended provisions enter into force.

Article 5 (Applicability to Labeling of Containers of Quasi-Drugs)

The amended provisions of Articles 65 (1) shall apply to quasi-drugs manufactured or imported after this Act enters into force.

Article 6 (Applicability to Succession to Status of Persons with Approval of Clinical Trial Protocols)

The amended provisions of Article 89 (1) shall begin to apply where a person who has obtained approval of a clinical trial protocol dies, transfers his or her business, or merges with another corporation after this Act enters into force.

Article 7 (Transitional Measures concerning Approval of Clinical Trial Protocols or Modification Thereof)

Any person who has applied for or obtained approval of a protocol for a clinical trial or a bioequivalence test, or approval of modification thereof, pursuant to the main clause of the previous Article 34 (1) as at the time this Act enters into force, shall be deemed to have applied for or obtained approval of a clinical trial or any modification thereof with respect to the relevant clinical trial or bioequivalence test in accordance with the amended provisions of the main clause of Article 34 (1).

Article 8 (Transitional Measures concerning Institutions Conducting Clinical Trials)

(1) An institution conducting clinical trials designated by the Minister of Food and Drug Safety pursuant to the previous provisions as at the time this Act enters into force shall be deemed an institution conducting clinical trials designated by the Minister of Food and Drug Safety pursuant to the amended provisions of Article 34-2 (1) 1.

(2) Any medical institution, among the institutions conducting bioequivalence tests designated by the Minister of Food and Drug Safety pursuant to the previous provisions as at the time this Act enters into force, shall be deemed to an institution conducting clinical trials (limited to conducting bioequivalence tests) designated by the Minister of Food and Drug Safety pursuant to the amended provisions of Article 34-2 (1) 1: Provided, That such institution shall comply with the amended provisions of Article 34-2 within one year from the date this Act enters into force.

(3) Any analysis institution, among the institutions conducting bioequivalence tests designated by the Minister of Food and Drug Safety pursuant to the previous provisions as at the time this Act enters into force, shall be deemed an institution conducting the analysis of clinical trial samples (limited to conducting bioequivalence tests) designated by the Minister of Food and Drug Safety pursuant to the amended provisions of Article 34-2 (1) 2: Provided, That such institution shall comply with the amended provisions of Article 34-2 within one year from the date this Act enters into force.

(4) Any analysis or medical institution, among the institutions conducting bioequivalence tests designated by the Minister of Food and Drug Safety pursuant to the previous provisions as at the time this Act enters into force, shall be deemed an institution conducting clinical trials (limited to conducting bioequivalence tests) or an institution conducting the analysis of clinical trial samples (limited to conducting bioequivalence tests) designated by the Minister of Food and Drug Safety pursuant to the amended provisions of Article 34-2 (1) 1 and 2: Provided, That such institution shall comply with the amended provisions of Article 34-2 within one year from the date this Act enters into force.

Article 9 (Transitional Measures concerning Labeling of Containers of Quasi-Drugs)

Notwithstanding the amended provisions of Articles 65 (1) and 65-2 through 65-4, and the latter part of Article 66, the containers, packages, and package inserts with the labeling prescribed in the previous Articles 65, 65-2, and 66 may be used under the previous provisions for one year from the date this Act enters into force.

Article 10 (Transitional Measures concerning Penalty Provisions)

The previous provisions shall apply to any violation committed before this Act enters into force.

Article 11 (Transitional Measures concerning Administrative Fines)

The previous provisions shall apply to administrative fines for any violation committed before this Act enters into force.

ADDENDA <*Act No. 15534, Mar. 27, 2018*>

Article 1 (Enforcement Date)

This Act shall enter into force on January 1, 2020. (Proviso Omitted.)

Article 2 Omitted.

ADDENDA <*Act No. 15709, Jun. 12, 2018*>

Article 1 (Enforcement Date)

This Act shall enter into force on October 25, 2018: Provided, That the amended provisions of Articles 85-4 and 92-2 shall enter into force on the date of its promulgation.

Article 2 (Applicability to Preparation of Records on Clinical Trials)

The amended provisions of Articles 34-2 (3) 3, 76-2 (1) 2, and 95 (1) 6-2 of the Pharmaceutical Affairs Act (Act No. 14926) shall begin to apply to cases of obtaining approval of protocols for clinical trials (including cases of obtaining approval of modification) after this Act enters into force.

Article 3 (Applicability to Exemption of Obligation to Retain and Keep Records)

The amended provisions of Article 85-4 shall also apply where any record is destroyed due to a natural disaster or other force majeure circumstances before this Act enters into force.

ADDENDA <*Act No. 15891, Dec. 11, 2018*>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation: Provided, That the amended provisions of subparagraph 1 of Article 5, Articles 24 (2) 2, 31 (3) 4, 34 (3) 5, 34-2 (3) 5 and paragraphs (4) and (5) of that Article, and 53 (1), subparagraph 2 of Article 60, Article 61 (1) 2, subparagraph 2 of Article 62, and Articles 66, 68 (5), 76-2 (1) 2 and 3, 86-2 (4), 91 (1), 92 (1), 92-2, 93 (1) 4, 10 and 11, and 95 (1) 6-2 and 6-4 shall enter into force on the date of its promulgation; the amended provisions of Articles 68-3, and 91 (3) through (6) shall enter into force three months after the date of its promulgation; and the amended provisions of Article 34 (3) 6; the proviso of 34-2 (3), with the exception of its subparagraphs, and subparagraphs 2 through 4 of that paragraph, and Articles 85, 94 (1) 3, 95 (1) 6-3, and 98 (1) 10 and 10-2 shall enter into force six months after the date of its promulgation.

Article 2 (Preparation for Establishment and Operation of Integrated Drug Information System)

The Minister of Food and Drug Safety may make necessary preparations to establish, operate, etc. an integrated drug information system referred to in the amended provisions of Article 83-5 before this Act enters into force.

Article 3 (Applicability to Matters to Be Observed by Persons Intending to Conduct Clinical Trials)

The amended provisions of Article 34 (3) 5 and 6 shall begin to apply to persons who intend to conduct clinical trials after obtaining approval from the Minister of Food and Drug Safety pursuant to Article 34 (1) after the same amended provisions enter into force.

Article 4 (Applicability to Matters to Be Observed by Institution Conducting Clinical Trials)

The amended provisions of Article 34-2 (3) 3 and 4 shall begin to apply to clinical trials conducted by institutions conducting clinical trials designated by the Minister of Food and Drug Safety pursuant to Article 34-2 (1) after the same amended provisions enter into force.

Article 5 (Applicability to Imposition of Penalty Surcharges)

The amended provisions of Article 81-2 (1) shall begin to apply to violations of Article 31 (2), (3) or (9), or 42 (1), subparagraph 3 of Article 60, or Article 62, committed after this Act enters into force.

Article 6 (Transitional Measures concerning Registration of Overseas Manufacturing Factories by Importers)

Any importer required to be registered under the amended provisions of Article 42 (6) as at the time this Act enters into force may continue to import drugs, etc. without registration prescribed in the same amended provisions until one year from the date this Act enters into force.

Article 7 (Transitional Measures concerning Modification of Articles of Association)

The articles of association of the Korea Institute of Drug Safety and Risk Management or the Korea Orphan and Essential Drug Center as at the time the amended provisions of Articles 68-3 (3) and 91 (3) enter into force shall be deemed the articles of association under the same amended provisions: Provided, That where the existing articles of association fails to comply with the same amended provisions, such articles of association shall be amended and authorized by the Minister of Food and Drug Safety within three months from the date such amended provisions enter into force.

ADDENDA <*Act No. 16250, Jan. 15, 2019*>

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 31, 36 (4), 40 (4), 41 (2), 42, and 45 (6) shall enter into force on the date of its promulgation; the amended provisions of Article 3 (2) 2 shall enter into force one year after the date of its promulgation; and the amended provisions of Articles 42 (6) through (9), and 76 (1) 5-3 and 5-4 of the Pharmaceutical Affairs Act (Act No. 15891) and Article 6 of the Addenda shall enter into force on December 12, 2019.

Article 2 (Transitional Measures concerning Qualification for Taking National Examinations for Pharmacist License)

Any person qualified to take a national examination for a pharmacist license under the previous Article 3 (2) 2 as at the time this Act enters into force shall be deemed qualified for the same under this Act.

Article 3 (Transitional Measures concerning Composition of the Central Pharmaceutical Affairs Advisory Committee)

(1) Where the amended provisions of the latter part of Article 18 (2) are not complied with as at the time of appointing or commissioning a member after this Act enters into force, a member who is not a public official shall be commissioned until the requirements prescribed in the relevant amended provisions are satisfied.

(2) The previous provisions shall apply to the composition of the members of the Central Pharmaceutical Affairs Advisory Committee until the amended provisions of the latter part of Article 18

(2) are complied with pursuant to paragraph (1).

Article 4 (Transitional Measures concerning Penalty Surcharges)

Notwithstanding the amended provisions of Article 81 (1), the previous provisions shall apply to the imposition of penalty surcharges for violations committed before this Act enters into force.

Article 5 Omitted.

ADDENDA *<Act No. 16556, Aug. 27, 2019>*

Article 1 (Enforcement Date)

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

Articles 2 through 8 Omitted.

ADDENDA *<Act No. 17091, Mar. 24, 2020>*

Article 1 (Enforcement Date)

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

Articles 2 through 5 Omitted.

ADDENDA *<Act No. 17208, Apr. 7, 2020>*

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 76 (1), 83-7, 93 (1) 4-2, 4-3, 5-2, 8-2, 8-3, 94 (1) 3-2 and 95 (1) 1 shall enter into force on the date of its promulgation. The amended provisions of subparagraphs 1-2 shall enter into force three months after the date of its promulgation; the amended provisions of Articles 7, 79, and 98 (1) 1 and 2 shall enter into force one year after the date of its promulgation; the amended provisions of Articles 83-3 through 83-6 shall enter into force three years after the date of its promulgation; and the amended provisions of Article 3 shall enter into force five years after the date of its promulgation..

Article 2 (Transitional Measures concerning Qualification for Taking National Examinations for Pharmacist Licenses)

(1) The amended provisions of Article 3 shall apply to persons who enter a college of pharmacy after the results of certification by university or college are disclosed at least once after conducting examination for certification prescribed in Article 11-2 (2) of the Higher Education Act on all universities that major in pharmacy.

(2) Notwithstanding the amended provisions of Articles 3 and 1, the previous provisions shall apply to those who enroll before certified or non-certified schools specializing in medical science, dentistry, oriental medical science or nursery are announced once or more under paragraph (1).

Article 3 (Applicability to Cancellation of License)

The amended provisions of Article 76 (1) shall also apply where permission, permission for modification, approval or approval for modification has been obtained, or registration, registration of modification, a report, or a report on modification has been filed by fraud or other improper means before the same amended provisions enter into force.

Article 4 (Transitional Measures concerning Reporting of Pharmacists and Oriental Pharmacists)

(1) A person who has obtained a pharmacist or oriental medicine pharmacist license before the amended provisions of Article 7 enter into force shall report the actual conditions, such as employment status, within one year after the same amended provisions enter into force.

(2) Where a person who obtained a pharmacist or oriental medicine pharmacist license before the amended provisions of Article 7 enter into force fails to file a report under paragraph (1), the Minister of Health and Welfare may suspend the validity of the license from the time when the report period terminates until the time when he or she makes a report.

Article 5 (Transitional Measures concerning Administrative Fines)

The previous provisions shall govern when applying the provisions of administrative fines to acts committed before the enforcement of the amended provisions of subparagraphs 1 and 2 of Article 98 (1).

ADDENDA *<Act No. 17472, Aug. 11, 2020>*

Article 1 (Enforcement Date)

This Act shall enter into one month after the date of its promulgation: Provided, That ⋯ *<omitted>* ⋯ *the amended provisions of any Act, which is amended pursuant to Article 4 of the Addenda and promulgated before this Act enters into force but the enforcement date of which has yet to arrive, shall enter into force on the enforcement date of such Act.*

Articles 2 through 5 Omitted.

ADDENDA *<Act No. 17883, Jan. 5, 2021>*

Article 1 (Enforcement Date)

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

Articles 2 through 9 Omitted.

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