ENFORCEMENT DECREE OF THE PHARMACEUTICAL AFFAIRS ACT

[Enforcement Date 01. Nov, 2019.] [Presidential Decree No.30170, 29. Oct, 2019., Amendment by Other Act]

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ENFORCEMENT DECREE OF THE PHARMACEUTICAL AFFAIRS ACT

[Enforcement Date 01. Nov, 2019.] [Presidential Decree No.30170, 29. Oct, 2019., Amendment by Other Act]

Article 1 (Purpose) The purpose of this Decree is to prescribe the matters mandated by the Pharmaceutical Affairs Act and those necessary for enforcing said Act.

Article 2 (Administration of National Examinations for Pharmacist License or Oriental Medicine Pharmacist License) (1) Pursuant to Article 8 (2) of the Pharmaceutical Affairs Act (hereinafter referred to as the "Act"), the Minister of Health and Welfare shall require the Korea Health Personnel Licensing Examination Institute established under the Korea Health Personnel Licensing Examination Institute Act (hereinafter referred to as "national examination administrative agency") to manage a national examination for a pharmacist license or oriental medicine pharmacist license (hereinafter referred to as "national examination"). <Amended by Presidential Decree No. 26742, Dec. 22, 2015>

(2) Where the head of the national examination administrative agency intends to administer a national examination, he or she shall, with prior approval from the Minister of Health and Welfare, publicly announce the date and time, places, and subjects of the examination, the deadline for submission of an application for the examination, and other matters necessary for the examination, no later than 90 days before the date of the examination: Provided, That he or she may publicly announce the places of the examination no later than 30 days before the examination date after the number of applicants for the examination for each region is determined. <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23759, May 1, 2012>

Article 3 (Application for National Examination) (1) Any person who intends to apply for a national examination shall submit to the head of the national examination administrative agency a written application prescribed by the head of the national examination administrative agency.

(2) "Foreign college of pharmacy accredited by the Minister of Health and Welfare" in Article 3 (2) 2 of the Act means a college equivalent to or higher than those prescribed by Article 3 (2) 1 of the Act with respect to its curriculum or educational system. <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>

(3) Any person who submits a written application pursuant to paragraph (1) shall pay in cash a fee determined by the head of the national examination administrative agency with approval from the Minister of Health and Welfare. In such cases, the amount and payment method of the fee and other necessary

matters shall be publicly announced by the head of the national examination administrative agency pursuant to Article 2. <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23459, Dec. 30, 2011>

(4) The head of the national examination administrative agency may have a fee referred to in paragraph (3) paid by means of electronic currencies, electronic settlement, etc. through the information and communications network. <Amended by Presidential Decree No. 23459, Dec. 30, 2011>

Article 4 (Subjects of Examinations) (1) A national pharmacist examination shall be administered in writing, covering the following subjects, and the details of subjects shall be prescribed by Ordinance of the Ministry of Health and Welfare:

1. Life science in pharmacy;
2. Industrial pharmacy;
3. Clinical pharmacy and pharmacy practice;
4. Regulations concerning health and pharmacy.

(2) A national oriental pharmacist examination shall be administered in writing, covering the following subjects and the details of subjects shall be prescribed by Ordinance of the Ministry of Health and Welfare:

1. Basics of oriental pharmacy;
2. Applied oriental pharmacy;
3. Regulations concerning health and pharmacy.

[This Article Wholly Amended by Presidential Decree No. 24775, Sep. 26, 2013]

Article 5 (Decision on Successful Candidate) A person who scores at least 40% in each subject and scores at least 60% on aggregate in all subjects shall be considered a successful candidate.

Article 6 (Announcement of Successful Candidates) Where the head of the national examination administrative agency decides on the successful candidates of the national examinations held under Articles 2 and 5, he or she shall announce the list of the successful candidates without delay.

Article 7 (Examiners) In order to give questions for the national examinations and mark papers thereof, the head of the national examination management agency shall commission examiners from among persons with much knowledge and experience in pharmacology or related statutes and regulations.

Article 8 (Request for Cooperation to Relevant Agencies) The head of the national examination management agency may request the State and local governments, or relevant agencies or organizations for the cooperation in examination places, examination proctors, etc., if necessary for the smooth administration of national examinations.

Article 8-2 (Composition of Ethics Committee) (1) The Ethics Committee to be established within the Korean Pharmaceutical Association (hereinafter referred

to as the "Pharmaceutical Association") and the Association of Korea Oriental Pharmacy (hereinafter referred to as the "Oriental Pharmacy Association") in accordance with Articles 11 (5) and 12 (5) of the Act shall be comprised of 11 members, including one chairperson.

(2) The chairperson shall be commissioned by the head of the Pharmaceutical Association or the Oriental Pharmacy Association (hereafter in this Article through Article 8-4, referred to as "each Association") from among the members of each Association.

(3) Members shall be commissioned by the head of each Association from among the following persons and shall include at least four persons who fall under subparagraph 2:

1. A member of each Association who has at least 10 years of experience as a pharmacist or five years of experience as an oriental medicine pharmacist;
2. A person who is not a pharmacist or oriental medicine pharmacist but has much knowledge and experience in law, health care, press, rights and interests of consumers, etc.

(4) The term of office of a member shall be three years and may be renewed only once.

[This Article Newly Inserted by Presidential Decree No. 23843, Jun. 7, 2012]

Article 8-3 (Operation of Ethics Committee) (1) The Ethics Committee shall deliberate and decide on the following matters: <Amended by Presidential Decree No. 28820, Apr. 24, 2018>

1. Matters concerning the request for disposition of license revocation or qualification suspension under the subparagraphs of Article 79-2 (1) of the Act;?
2. Matters concerning the review of qualifications of, and the disciplinary actions against, members of each Association;
3. Other matters necessary for the establishment of a code of ethics of members, which are prescribed by the articles of association of each Association.

(2) A meeting of the Ethics Committee shall be convened by the chairperson where deemed necessary by the chairperson or where requested by the head of each Association or not less than 1/3 of its incumbent members.

(3) In convening a meeting, the chairperson shall notify each member of the date and time, venue, and agenda items of the meeting no later than seven days before the opening of the meeting: Provided, That where an urgent meeting is required or where any unavoidable reason exists, the chairperson may notify such matters by the day before the meeting.

(4) At least 2/3 of the members of the Ethics Committee shall constitute a quorum, and any decision thereof shall require the concurrent vote of at least 2/3 of those present: Provided, That the quorum for the matters referred to in paragraph (1) 2 and 3 shall be separately prescribed by the articles of

association of each Association.

(5) Where the chairperson of the Ethics Committee intends to deliberate and decide on the matters referred to in paragraph (1) 1 or 2, he or she shall give a party to the relevant agenda item an opportunity to state his or her opinion orally or in writing (including electronic documents).

(6) Except as provided in paragraphs (1) through (5), matters necessary for the operation of each Ethics Committee shall be prescribed by the articles of association of each Association.

[This Article Newly Inserted by Presidential Decree No. 23843, Jun. 7, 2012]

Article 8-4 (Disqualification of Members of Ethics Committee) (1) A member of the Ethic Committee who falls under any of the following subparagraphs shall be disqualified from deliberations and decisions of the relevant Ethics Committee:

1. Where he or she becomes a party to the agenda item to be deliberated and decided by the Ethics Committee (hereafter in this Article, referred to as "relevant agenda item");
2. Where he or she is or was a relative of a party to the relevant agenda item;
3. Where he or she engages in or has engaged in an institution to which a party to the relevant agenda item belongs in the recent three years.

(2) If there exists any ground for disqualification referred to in paragraph (1) or the circumstances indicate that it would be impracticable to expect fair deliberations and decisions by the Ethics Committee, a party to the relevant agenda item may file a written request for a challenge to the relevant member with the Ethics Committee by stating the reasons therefor.

(3) Upon receipt of the request for the challenge under paragraph (2), the Ethics Committee shall determine whether or not to accept the challenge with the attendance of a majority of all the incumbent members and the concurring vote of a majority of those present. In such cases, the member against whom the request for challenge is filed shall not participate in such decision.

(4) If any member of the Ethics Committee falls under any ground referred to in paragraph (1) or (2), he or he may voluntarily refrain from deliberations and decisions.

[This Article Newly Inserted by Presidential Decree No. 23843, Jun. 7, 2012]

Article 9 (Authorization for Establishment of the Pharmaceutical Association and the Oriental Pharmacy Association) If the Pharmaceutical Association or the Oriental Pharmacy Association intends to obtain authorization for establishment under Article 13 (1) of the Act, it shall submit the following documents to the Minister of Health and Welfare: <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23843, Jun. 7, 2012>

1. The articles of association;
2. The detailed statement of assets;

3. A business plan and a budget of revenues and expenditures;
4. A resolution of establishment;
5. Documents regarding the election process for establishment representatives;
6. A letter of acceptance of appointment and a resume of an executive officer.

Article 10 (Matters to Be Included in Articles of Association) Matters to be included in the articles of association of the Pharmaceutical Association or the Oriental Pharmacy Association shall be as follows: <Amended by Presidential Decree No. 23843, Jun. 7, 2012>

1. The objectives;
2. The title;
3. The principal office;
4. Matters concerning assets and accounting;
5. Matters concerning appointment of executive officers;
6. Matters concerning qualification and discipline of members;
7. Matters concerning amendments to the articles of association;
8. Matters concerning method of public announcement;
9. Matters concerning operation, etc. of the Ethics Committee.

Article 11 (Application for Authorization for Modification of Articles of Association) If the Pharmaceutical Association or the Oriental Pharmacy Association intends to obtain authorization for the modification of its articles of association under Article 13 (3) of the Act, it shall submit the following documents:

1. Details of and reasons for modification of its articles of association;
2. Minutes concerning modification of its articles of association;
3. Comparison table of its new and old articles of association, and other reference documents.

Article 12 (Establishment of Chapters) The Pharmaceutical Association or the Oriental Pharmacy Association shall establish its chapters in the Special Metropolitan City, Metropolitan Cities, Dos, and the Special Self-Governing Province under Article 14 of the Act within three weeks from the date of registration for establishment.

Article 13 (Functions of the Central Pharmaceutical Affairs Advisory Committee) The Central Pharmaceutical Affairs Advisory Committee (hereafter in Articles 14-2, 14-3, 15 through 20, 20-2, 21 and 22, referred to as the "Advisory Committee") referred to in Article 18 (1) of the Act shall deliberate on the following matters: <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23459, Dec. 30, 2011; Presidential Decree No. 24479, Mar. 23, 2013; Presidential Decree No. 25605, Sep. 11, 2014; Presidential Decree No. 29811, Jun. 4, 2019; Presidential Decree No. 29983, Jul. 16, 2019>

1. Matters concerning the enactment and amendment of the Korean

Pharmacopoeia prescribed in Article 51 of the Act;
2. Matters concerning the standards for drugs and quasi-drugs (hereinafter referred to as "drugs, etc") prescribed in Article 52 of the Act;
3. Matters concerning the investigation, research, and evaluation of safety and effectiveness of drugs, etc.;
4. Matters concerning the relief of injury from side effects of drugs;
5. Matters concerning the classification of over-the-counter drugs and prescription drugs;
6. Other matters to be brought to deliberation by the Minister of Health and Welfare or the Minister of Food and Drug Safety.

Article 14 Deleted. <by Presidential Decree No. 29811, Jun. 4, 2019>

Article 14-2 (Dismissal of Members of the Advisory Committee) Where a member of the Advisory Committee commissioned pursuant to Article 18 (4) of the Act falls under any of the following subparagraphs, the Minister of Food and Drug Safety may dismiss the member: <Amended by Presidential Decree No. 28081, May 29, 2017; Presidential Decree No. 29811, Jun. 4, 2019>
1. Where the member is unable to perform the duties due to mental or physical disability;
2. Where the member commits a misdeed in connection with his or her duties;
3. Where the member is deemed unsuitable as a member due to neglect of duties, injury to dignity, or other causes;
4. Where the member admits that it is impracticable to voluntarily perform the duties;
5. Where the member fails to refrain from himself or herself, though he or she falls under any of the subparagraphs of Article 14-3 (1).

[This Article Newly Inserted by Presidential Decree No. 26844, Dec. 31, 2015]

Article 14-3 (Disqualification of, Challenge to, and Refrainment by, Members of the Advisory Committee) (1) Any member of the Advisory Committee who falls under any of the following subparagraphs shall be disqualified from deliberations and decisions of the Advisory Committee:
1. Where the member or his or her spouse or ex-spouse is a party (including where he or she is related to a party as a co-obligee or co-obligor; hereinafter the same shall apply) to the relevant agenda item;???
2. Where the member is or was a relative of a party to the relevant agenda item;
3. Where the member has offered any testimony, statement, advice, research, services, or appraisal for the relevant agenda item;??
4. Where the member or the corporation to which the member belongs is or was an agent of a party to the relevant agenda item;?
5. Cases corresponding to subparagraphs 1 through 4, where the Chairperson or the Vice Chairperson deems that the member has a direct interest in the

relevant agenda item.

(2) If the circumstances indicate that it would be impracticable to expect fair deliberations and decisions of a member, a party may file a request for a challenge to the member with the Advisory Committee by explaining the relevant fact in writing.??

(3) Upon receipt of a request for challenge under paragraph (2), the Advisory Committee shall determine whether or not to accept the request by decision. In such cases, the member against whom the request for challenge is filed shall not participate in the decision.??

(4) If a member falls under any of the grounds prescribed in the subparagraphs of paragraph (1) or finds himself or herself to be in the circumstances under which it would be impracticable to expect fair deliberations and decisions, he or she shall voluntarily refrain from deliberations and decisions on the relevant agenda item.

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 15 (Duties of Chairperson) (1) The Chairperson shall exercise general supervision over the affairs of the Advisory Committee and represent the Advisory Committee. <Amended by Presidential Decree No. 23459, Dec. 30, 2011>

(2) Vice Chairpersons shall assist the Chairperson, and the Vice Chairperson appointed by the Chairperson shall act on behalf of the Chairperson where the Chairperson is unable to perform the duties due to unavoidable reasons.

Article 16 (Convocation of Meetings) (1) The Chairperson shall convene and preside over meetings of the Advisory Committee.

(2) The Chairperson shall convene a meeting of the Advisory Committee without delay when requested by the Minister of Health and Welfare, the Minister of Food and Drug Safety, or a majority of the incumbent members. <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>

Article 17 (Subcommittees) (1) Subcommittees and sectional committees may be established within the Advisory Committee, if necessary.

(2) Matters relating to organization and operation of the subcommittees and sectional committees under paragraph (1) shall be determined by the Minister of Food and Drug Safety following consultation with the Minister of Health and Welfare. <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>

Article 18 (Proceedings) (1) A majority of the members of the Advisory Committee shall constitute a quorum, and any decision thereof shall require the concurring vote of at least 2/3 of those present.

(2) Matters deliberated by the subcommittees or sectional committees shall be

deemed decided by the Advisory Committee, except where the Chairperson of the Advisory Committee determines that it is necessary for another committee to re-deliberate the matters.

Article 19 (Reporting) The Chairperson shall without delay report matters deliberated by the Advisory Committee to the Minister of Food and Drug Safety and shall without delay inform the Minister of Health and Welfare of the matters to be brought to deliberation by the Minister of Health and Welfare under subparagraph 6 of Article 13. <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>

Article 20 (Research Committee Members) (1) Not more than 10 research committee members shall, in advance, be assigned to the Advisory Committee.

(2) The research committee members shall investigate and research in advance matters to be deliberated by the Advisory Committee, following an order from the Chairperson.

(3) The research committee members may attend and speak at meetings of the Advisory Committee.

(4) The Advisory Committee shall assign not more than 10 researchers to assist the research committee members.

(5) The research committee members and researchers referred to in paragraphs (1) and (4) shall be appointed by the Minister of Food and Drug Safety from among persons who have much knowledge and experience in pharmaceutical affairs. <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>

Article 20-2 (Hearing of Opinions) If necessary in connection with deliberation by the Advisory Committee, the Chairperson may require a relevant expert who has expertise and experience in pharmaceutical affairs to attend the relevant meetings to hear his or her opinion. <Amended by Presidential Decree No. 29983, Jul. 16, 2019>

[This Article Newly Inserted by Presidential Decree No. 29811, Jun. 4, 2019]

Article 21 (Executive Secretary and Clerks) (1) One executive secretary and several clerks shall be assigned to the Advisory Committee.

(2) The executive secretary and clerks shall be appointed by the Minister of Food and Drug Safety from among public officials of the Ministry of the Food and Drug Safety. <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>

(3) The executive secretary shall perform administrative affairs of the Advisory Committee following an order from the Chairperson, and clerks shall assist the executive secretary.

Article 22 (Allowances and Traveling Expenses) The Minister of Food and Drug Safety may pay allowances and traveling expenses to the members of the Advisory Committee, subcommittees, and sectional committees, and research expenses and traveling expenses to the research committee members and researchers, respectively, within budgetary limits. <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>

Article 22-2 (Standards for Facilities of Pharmacies) (1) A pharmacy shall be equipped with the following facilities under Article 20 (3) of the Act:

1. A dispensary;
2. A facility for low-temperature storage and sun screen;
3. A facility for providing tap water or underground water, etc. that satisfies the quality standards for drinking water under Article 5 of the Drinking Water Management Act;
4. Devices necessary for dispensing drugs.

(2) Detailed standards for facilities under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare following consultation between the Minister of Health and Welfare and the Minister of Food and Drug Safety.
[This Article Newly Inserted by Presidential Decree No. 24479, Mar. 23, 2013]

Article 23 (Scope of Direct Dispensing by Physicians or Dentists) "Cases prescribed by Presidential Decree" in Article 23 (4) 14 of the Act means any of the following cases: <Amended by Presidential Decree No. 20875, Jun. 25, 2008; Presidential Decree No. 21084, Oct. 14, 2008; Presidential Decree No. 23459, Dec. 30, 2011; Presidential Decree No. 23734, Apr. 17, 2012; Presidential Decree No. 23886, Jun. 27. 2012; Presidential Decree No. 24247, Dec. 21, 2012; Presidential Decree No. 27673, Dec. 13, 2016>

1. Where physicians or dentists, who serve in military medical facilities under Article 15 of the Act on the Organization of National Armed Forces, dispense drugs for patients who are soldiers under Article 4 of that Act in the course of performing their duties;
2. Where physicians or dentists, who serve in the National Police Hospital under Article 31 of the Regulations on the Organization of Office of the National Police Agency and Its Affiliated Agencies or in the Central Fire Fighter Treatment Center under Article 7 of the Enforcement Decree of the Framework Act on Health, Safety and Welfare of Fire Officials, dispense drugs for patients who are police officers or fire officials in the course of performing their duties;
3. Where physicians or dentists, who serve in medial institutions established and operated by the Korea Workers' Compensation and Welfare Service pursuant to Article 11 (2) of the Industrial Accident Compensation Insurance Act, dispense, in the course of performing their duties, drugs for patients suffering

from pneumoconiosis from among persons who had occupational accidents under subparagraph 1 of Article 5 of that Act;

4. Where physicians or dentists, who serve in the Korea Veterans Hospital established under Article 7 of the Korea Veterans Welfare and Healthcare Corporation Act, dispense drugs for patients for whom the total amount of medical expenses is borne by the State pursuant to the Act on the Honorable Treatment and Support of Persons, etc. of Distinguished Services to the State, the Act on Support for Persons Eligible for Veteran's Compensation, the Act on Assistance to Patients Suffering from Actual or Potential Aftereffects of Defoliants, etc. and Establishment of Related Organizations, and the Act on the Honorable Treatment of Persons of Distinguished Services to the May 18 Democratization Movement in the course of performing their duties;
5. Where physicians or dentists, who serve in a health room under Article 3 of the School Health Act (excluding those who serve in a medical institution established in the relevant school under the Medical Service Act), dispense drugs for patients who are students or teaching staff of the relevant school in the course of performing their duties;
6. Where physicians or dentists, who are health managers under Article 16 of the Industrial Safety and Health Act (excluding those who serve in a medical institution established in the relevant workplace under the Medical Service Act), dispense drugs for patients who are workers of the relevant workplace in the course of performing their duties;
7. Where physicians or dentists dispense drugs for foreign patients pursuant to Article 27 (3) 2 of the Medical Service Act.

Article 24 (Similar Collusive Acts) (1) "Other acts prescribed by Presidential Decree, which have the potential for collusion as being similar to any of those referred to in subparagraphs 1 through 4" in Article 24 (2) 5 of the Act means the following acts: <Amended by Presidential Decree No. 29950, Jul. 2, 2019>

1. An act of making dispensing available only at a specific pharmacy by stating the names, etc. of drugs on a prescription with a symbol or code pursuant to a prearrangement between a pharmacy founder and a medical institution founder;
2. An act, performed by a medical institution founder, of making dispensing available only at a specific pharmacy by prescribing the drugs not in the list of prescription drugs under Article 25 of the Act;
3. An act, performed together by a pharmacy founder and a medical institution founder, of supporting or managing the affairs of purchasing drugs, dispensing drugs, filing applications for the review of the costs of health care benefits, etc. under the National Health Insurance Act;
4. An act, performed by a medical institution founder, of transmitting the prescription by utilizing a facsimile or computer communications, etc. so as to make dispensing available at a specific pharmacy without any request from the holder of such prescription;

5. The act, performed by a medical institution founder, of ordering a pharmacist under his or her de facto control and supervision to establish a pharmacy, or of operating a pharmacy actually by controlling or supervising a pharmacist who has established the pharmacy.

(2) The Minister of Health and Welfare, the Special Metropolitan City Mayor, a Metropolitan City Mayor, a Do Governor, or a Special Self-Governing Province Governor (hereinafter referred to as the "Mayor/Do Governor"), or 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) shall require relevant public officials to conduct an inspection under Article 69 of the Act on a medical institution founder or a pharmacy founder in accordance with the standards determined by the Minister of Health and Welfare in order to prevent any collusive act under Article 24 (2) of the Act, in any of the following cases: <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>

1. Where it is considered that a medical institution founder (if a medical institution founder is a corporation, including the executive officers of such corporation) and a pharmacy founder have the relationship of spouse, parent, sibling, child, or child' s spouse and that the relevant pharmacy exclusively induces prescriptions issued by the relevant medical institution;
2. Where a medical institution and a pharmacy are installed in the same building with the same entrance and it is considered that the relevant pharmacy exclusively induces the prescriptions issued by the relevant medical institution.

Article 24-2 (Entrustment of Affairs of Registrating Drug Identification Mark) (1) "Relevant specialized institution prescribed by Presidential Decree" in Article 38-2 (3) of the Act means a corporation designated and publicly notified by the Minister of Food and Drug Safety, among drug-related corporations established with permission from the Minister of Food and Drug Safety, pursuant to Article 32 of the Civil Act.

(2) Where the Minister of Food and Drug Safety entrusts the affairs pursuant to Article 38-2 (3) of the Act, he or she shall publicly notify an entity entrusted and the details of affairs.

[This Article Newly Inserted by Presidential Decree No. 26544, Sep. 22, 2015]

Article 25 (Examination for Herb Druggists) The examination for herb druggists provided for in Article 45 (3) of the Act shall be administered by the Mayor/Do Governor with regard to the knowledge necessary for the handling of herbal drugs and their working-level functions.

Article 26 (Eligibility Requirements for Examination) A person with at least five years of career in handling of herbal drugs at an oriental medical clinic or an herb drugstore, who has graduated from a high school or higher educational institution or who is recognized by the Minister of Education as one with

educational attainment equal to or higher than such school shall be entitled to apply for the examination for herb druggists.

[This Article Wholly Amended by Presidential Decree No. 29983, Jul. 16, 2019]

Article 27 (Subjects of Examination and Allotting Percentage) The examination for herb druggists shall be classified into a written examination and a practical examination, and the subjects of the examination and allocated examination percentage shall be as follows:

[This Article Wholly Amended by Presidential Decree No. 29950, Jul. 2, 2019]

Article 28 (Public Announcement of Examination) Where the Mayor/Do Governor administers the examination for herb druggists, he or she shall publicly announce the date and time, place of the examination, subjects of the examination, deadline for submission of applications, an area where business permission is expected to be granted, the expected number of persons who obtain such permission, and other matters necessary for the examination, no later than 30 days before the examination date.

Article 29 (Application Form) (1) A person who intends to apply for the examination for herb druggists shall submit an application form to the Mayor/Do Governor, along with the following documents: <Amended by Presidential Decree No. 21084, Oct. 14, 2008>

1. A resume;
2. Documents evidencing educational attainment and career experience under Article 26;
3. A medical certificate issued by a physician evidencing that an applicant does not fall under the main clause of subparagraph 1 of Article 5 of the Act or a medical certificate issued by a medical specialist evidencing that an applicant falls under the proviso of subparagraph 1 of Article 5 of the Act;
4. A medical certificate issued by a physician evidencing that an applicant does not fall under subparagraph 3 of Article 5 of the Act;
5. The expected place of business and a rough map thereof.

(2) A person who submits an application form under paragraph (1) shall pay a fee, as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>

Article 30 (Determination of Successful Applicants) (1) After administering the examination for herb druggists, the Mayor/Do Governor shall determine applicants who score at least 60 percent on aggregate in all subjects, as successful applicants within the limit of expected number of those to be granted permission for each area where business permission is expected to be granted as publicly announced under Article 28: Provided, That where there are not less than two persons with a tie score, exceeding the expected number of those to be granted permission for each area where business permission is expected to be

granted, the person with a higher score on the written examination shall be chosen, and even where there is a tie score on the written examination, all the persons with a tie score shall be chosen as successful applicants.

(2) The Mayor/Do Governor shall inform the successful applicants under paragraph (1) of their passing of the examination.

Article 31 (Examination Committee Members) (1) The Mayor/Do Governor shall appoint examination committee members from among persons who have much knowledge and experience in herbal drugs and who have substantial knowledge of statutes and regulations on pharmaceutical affairs and narcotics.

(2) The examination committee under paragraph (1) shall consist of two to five persons per subject.

Article 31-2 (Standards for Facilities of Herb Druggists and Drug Wholesalers) (1) Detailed standards for a business place that an herb druggist is required to be equipped with under Article 45 (2) 1 of the Act shall be prescribed by Ordinance of the Ministry of Health and Welfare following consultation between the Minister of Health and Welfare and the Minister of Food and Drug Safety.

(2) In accordance with Article 45 (2) 2 of the Act, a drug wholesaler shall be equipped with a business place and a warehouse prescribed by Ordinance of the Ministry of Health and Welfare following consultation between the Minister of Health and Welfare and the Minister of Food and Drug Safety and shall own assets prescribed by Ordinance of the Ministry of Health and Welfare for the operation, etc. of the relevant facilities: Provided, That a medical high-pressure gas wholesaler shall comply with the standards for facilities for the sales of high-pressure gas under Article 4 (4) of the High-Pressure Gas Safety Control Act, and a radiopharmaceuticals wholesaler shall comply with the standards for facilities for radioisotope sales business under Article 55 (1) of the Nuclear Safety Act.

(3) Notwithstanding the main clause of paragraph (2), a drug wholesaler need not be equipped with a warehouse, if he or she entrusts the management of distribution, such as storage and delivery, of drugs to another drug wholesaler who meets the requirements prescribed by Ordinance of the Ministry of Health and Welfare.

(4) If a druggist or drug seller referred to in Article 5 of the Addenda to the Pharmaceutical Affairs Act (Act No. 8365) intends to operate his or her business, he or she shall be equipped with a business place prescribed by Ordinance of the Ministry of Health and Welfare following consultation between the Minister of Health and Welfare and the Minister of Food and Drug Safety.

[This Article Newly Inserted by Presidential Decree No. 24479, Mar. 23, 2013]

Article 32 (Grounds for Retail or Distribution of Drugs by Persons Who Obtained Permission by Item of Drugs) "Ground prescribed by Presidential

Decree, such as cases for public interests" in Article 47 (1) 2 of the Act means grounds falling under attached Table 1-2.

[This Article Wholly Amended by Presidential Decree No. 27048, Mar. 22, 2016]

Article 32-2 (Designation of the Korea Pharmaceutical Information Service)

The Minister of Health and Welfare shall designate the Health Insurance Review and Assessment Service under Article 62 of the National Health Insurance Act as an agency managing information on the distribution of drugs (hereinafter referred to as the "Korea Pharmaceutical Information Service") pursuant to Article 47-3 (1) of the Act. <Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24077, Aug. 31, 2012; Presidential Decree No. 28081, May 29, 2017>

[This Article Newly Inserted by Presidential Decree No. 21084, Oct. 14, 2008]

Article 32-3 (Operation of the Korea Pharmaceutical Information Service)

(1) The Korea Pharmaceutical Information Service shall perform the following affairs: <Amended by Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 27048, Mar. 22, 2016; Presidential Decree No. 28081, May 29, 2017>

1. Collection, investigation, processing, utilization, and provision of drug distribution information;
2. Formulation and implementation of a basic plan for informatization on the distribution of drugs;
3. Construction and operation of database of drug distribution information;
4. Management of bar codes or RFID tags of drugs determined by the Minister of Health and Welfare, such as a public announcement of drug standard codes [referring to serial numbers imposed on each drug for identification thereof, which are numbers in 13 figures, including country identification code; identification code of a person who has obtained permission by item of drugs (referring to the person who has obtained permission for manufacturing and distribution of items or filed a notification of manufacturing and distribution of items in accordance with Article 31 (2) or (3) of the Act; hereinafter the same shall apply) or of a person who has filed a notification of import business pursuant to the former part of Article 42 (1) of the Act (hereinafter referred to as "importer"); item code; and verification code];
5. Research, education, and public relations on standardization of drug distribution information;
6. Support of informatization on the distribution of drugs, such as the development and dissemination of programs necessary for the submission of supply details, etc. of drugs under Article 47-3 (2) of the Act;
7. Other matters recognized necessary by the Minister of Health and Welfare in connection with drug distribution information.

(2) The president of the Korea Pharmaceutical Information Service shall report,

to the Minister of Health and Welfare, a business plan for the affairs under paragraph (1), business performance, budget, and settlement of accounts of the relevant fiscal year by the deadline classified as follows: <Amended by Presidential Decree No. 22075, Mar. 15, 2010>

1. A business plan and budget of the relevant fiscal year: Not later than the commencement of the relevant fiscal year;
2. Business performance and settlement of accounts of the relevant fiscal year: Not later than the end of February of the following fiscal year.

(3) If necessary for the management of bar codes or RFID tags of drugs under paragraph (1) 4, the president of the Korea Pharmaceutical Information Service may require persons who have obtained permission by item of drugs or importers to submit a report on the product information of drugs which they intend to manufacture and distribute or import as determined and publicly notified by the Minister of Health and Welfare. <Amended by Presidential Decree No. 22075, Mar. 15, 2010>

[This Article Newly Inserted by Presidential Decree No. 21084, Oct. 14, 2008]

Article 32-4 (Fees for Providing Drug Distribution Information) (1) Where the Korea Pharmaceutical Information Service provides the processed information on distribution of drugs at the request of persons who have obtained permission by item of drugs, importers, drug wholesalers, etc. (excluding cases of disclosure to the public under subparagraph 2 of Article 2 of the Official Information Disclosure Act), it may receive fees from the relevant requester: Provided, That in any of the following cases, fees may be reduced or exempted: <Amended by Presidential Decree No. 22075, Mar. 15, 2010>

1. Where a State agency or a local government requests to provide drug distribution information in connection with the performance of affairs pursuant to statutes and regulations;
2. Where a non-profit corporation or a non-profit academic and public organization requests to provide drug distribution information for the purpose of academic research or administrative surveillance;
3. Where a requester makes a request for providing the information on distribution of the same drugs as that processed according to the same standards in the same year;
4. Other cases where the Minister of Health and Welfare recognizes that reduction or exemption of fees is necessary for public welfare, etc.

(2) Fees referred to in paragraph (1) shall be determined within the extent of actual expenses in consideration of expenses incurred in processing and providing drug distribution information, expenses incurred in developing programs necessary for the management of drug distribution information, etc.

(3) Fees referred to in paragraph (1) shall be paid in cash (including payment by methods of electronic currencies, electronic settlement, etc. through the information and communications network) to a financial institution or postal

service agency designated by the Korea Pharmaceutical Information Service.

(4) Matters necessary for the methods for requesting drug distribution information, and eligibility for and percentage of reduction or exemption of fees under paragraph (1), the specific methods for calculating fees under paragraph (2), etc. shall be determined and publicly notified by the Minister of Health and Welfare. <Amended by Presidential Decree No. 22075, Mar. 15, 2010>

[This Article Newly Inserted by Presidential Decree No. 21084, Oct. 14, 2008]

Article 32-5 (Grounds for Exceptions to Informing of Application for Permission by Item) "Cases prescribed by Presidential Decree" in Article 50-4 (1) 4 of the Act (including cases applied mutatis mutandis under Article 42 (5) of the Act) means cases where the registered patent information regarding medical usage referred to in Article 50-2 (4) 1 (d) of the Act is not relevant to the efficacy nor effectiveness of the drug for which an application for permission for manufacturing and distribution or import of items or permission for modification is filed pursuant to Article 31 (2), (3) or (9) or 42 (1) of the Act. <Amended by Presidential Decree No. 26544, Sep. 22, 2015>

[This Article Newly Inserted by Presidential Decree No. 26143, Mar. 13, 2015]

Article 32-6 (Entrustment of Affairs of Deliberation on Advertisement) The Minister of Food and Drug Safety shall entrust an incorporated association designated and publicly notified by him or her among incorporated associations established pursuant to Article 67 of the Act with deliberation on advertisement of drugs pursuant to Article 68-2 (2) of the Act. <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

[This Article Newly Inserted by Presidential Decree No. 20767, Apr. 10, 2008]

Article 32-7 (Organization and Operation of the Korea Institute of Drug Safety and Risk Management) (1) Directors and auditors, including the president, shall be appointed as executive officers for the Korea Institute of Drug Safety and Risk Management established under Article 68-3 of the Act (hereinafter referred to as the "Institute of Drug Safety and Risk Management").

(2) The president of the Institute of Drug Safety and Risk Management shall be appointed by the Minister of Food and Drug Safety, as prescribed by the articles of association. <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

(3) A board of directors shall be established within the Institute of Drug Safety and Risk Management in order to deliberate and decide on important matters concerning the affairs of the Institute of Drug Safety and Risk Management.

(4) Except as provided in paragraphs (1) through (3), matters necessary for the organization and operation of the Institute of Drug Safety and Risk Management shall be prescribed by the articles of association.

[This Article Newly Inserted by Presidential Decree No. 23459, Dec. 30, 2011]

Article 32-8 (For-Profit Projects) "For-profit projects prescribed by Presidential Decree" in Article 68-4, with the exception of its subparagraphs, of

the Act means any of the following projects: <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

1. Education and training of a person in charge of the affairs concerning drug safety information;
2. Production and distribution of publications, etc. related to drug safety information;
3. Other projects approved by the Minister of Food and Drug Safety to attain the establishment purposes of the Institute of Drug Safety and Risk Management.

[This Article Newly Inserted by Presidential Decree No. 23459, Dec. 30, 2011]

Article 32-9 (Approval of Business Plans and Budget Bills) (1) Where the Institute of Drug Safety and Risk Management intends to obtain approval of its business plan and budget bill pursuant to the former part of Article 68-6 (2) of the Act, it shall submit the budget bill accompanied by a business plan for the following year and the following documents to the Minister of Food and Drug Safety after decision by the board of directors, before each fiscal year begins: <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

1. An estimated balance sheet;
2. An estimated profit and loss statement;
3. A plan for revenue and expenditure.

(2) Where the Institute of Drug Safety and Risk Management intends to obtain approval of modification of a business plan and a budget bill pursuant to the latter part of Article 68-6 (2) of the Act, it shall submit a document stating the details of and grounds for modification to the Minister of Food and Drug Safety after decision by the board of directors. <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

[This Article Newly Inserted by Presidential Decree No. 23459, Dec. 30, 2011]

Article 32-10 (Documents for Access or Inspection by Drug Epidemiological Investigators) "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" in the latter part of Article 68-12 (3) of the Act means the following matters:

1. The purpose, period, scope, and details of the investigation;
2. Names and positions of persons in charge of the investigation;
3. A list of data that shall be submitted;
4. Basis statutes and regulations concerning the investigation;
5. Details and basis statutes and regulations concerning administrative dispositions or penalties against a refusal, obstruction, evasion, etc. of the investigation;
6. Matters corresponding to those falling under subparagraphs 1 through 5, which are deemed necessary by the Minister of Food and Drug Safety for the relevant investigation.

[This Article Newly Inserted by Presidential Decree No. 27673, Dec. 13, 2016]

Article 32-11 (Documents for Access or Investigation by Relevant Public Officials) "Matters prescribed by Presidential Decree, such as the period and scope of investigation, persons in charge of the investigation, and relevant statutes and regulations" in Article 69 (2) of the Act means the following matters:

1. Matters under subparagraphs 1 through 5 of Article 32-10;
2. Matters corresponding to those falling under subparagraph 1, which are deemed necessary by the Minister of Health and Welfare or the Minister of Food and Drug Safety for the relevant investigation.

[This Article Newly Inserted by Presidential Decree No. 27673, Dec. 13, 2016]

Article 32-12 (Informing Relevant Agencies) "Head of the relevant central administrative agency prescribed by Presidential Decree" in Article 69-2 of the Act means the following persons:

1. The Minister of Health and Welfare;
2. The Chairperson of the Fair Trade Commission;
3. The Commissioner of the Korean Intellectual Property Office.

[This Article Newly Inserted by Presidential Decree No. 26143, Mar. 13, 2015]

Article 33 (Standards for Calculation of Penalty Surcharges Imposed in Lieu of Disposition of Business Suspension) The amount of penalty surcharges under Article 81 (2) of the Act shall be calculated based on the standards prescribed in attached Table 2 according to the standards for the disposition of business suspension classified as follows, taking into consideration the types, degree, etc. of violations: <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013>

1. In cases of imposition of a penalty surcharge on a manufacturer of drugs, etc., a person who has obtained permission by item, or an importer: The standards prescribed by Ordinance of the Prime Minister;
2. In cases of imposition of a penalty surcharge on a pharmacy founder or a drug distributor: The standards prescribed by Ordinance of the Ministry of Health and Welfare.

Article 34 (Procedures for Imposition and Collection of Penalty Surcharges Imposed in Lieu of Disposition of Business Suspension) (1) If the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a Si/Gun/Gu intends to impose a penalty surcharge under Article 81 of the Act, he or she shall give written information of the payment thereof, stating the type of violation and the amount of penalty surcharge. <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

(2) Procedures for collecting penalty surcharges shall be subject to the following classification: <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

1. In cases of imposition of a penalty surcharge on a manufacturer of drugs, etc., a person who has obtained permission by item, or an importer: The procedures for collection prescribed by Ordinance of the Prime Minister;
2. In cases of imposition of a penalty surcharge on a pharmacy founder or a drug distributor: The procedures for collection prescribed by Ordinance of the Ministry of Health and Welfare.

Article 34-2 (Disposition to Defaulters of Penalty Surcharges Imposed in Lieu of Disposition of Business Suspension) (1) When a person fails to pay a penalty surcharge by the deadline for payment, the Minister of Food and Drug Safety, the Mayor/Do Governor, the head of a Si/Gun/Gu shall issue a demand for payment within 15 days after the elapse of the deadline for payment pursuant to the main clause of Article 81 (4) of the Act. In such cases, a new deadline for payment shall be within 10 days after the demand for payment is issued. <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

(2) If a person who fails to pay a penalty surcharge pursuant to paragraph (1) fails to pay it by the relevant payment deadline even after receipt of a demand for payment, a disposition to impose penalty surcharges shall be revoked and a disposition to suspend business shall be imposed: Provided, That where he or she falls under the proviso of Article 81 (4) of the Act, the penalty surcharge shall be collected in the same manner as delinquent national taxes are collected or pursuant to the Act on the Collection, etc. of Local Non-Tax Revenue. <Amended by Presidential Decree No. 25605, Sep. 11, 2014>

(3) Where a disposition to suspend business is imposed after the revocation of the disposition to impose a penalty surcharge pursuant to the main clause of paragraph (2), a person subject to the disposition shall be given written information, stating matters necessary for the disposition of business suspension, including grounds for the change of the disposition and a period for the suspension of business. <Amended by Presidential Decree No. 25605, Sep. 11, 2014>

[This Article Newly Inserted by Presidential Decree No. 20156, Jul. 3, 2007]

Article 34-3 (Standards for Imposing Penalty Surcharges for Manufacturing of Hazardous Drugs) The standards for imposing penalty surcharges pursuant to Article 81-2 (1) of the Act shall be as specified in attached Table 2-2.

[This Article Newly Inserted by Presidential Decree No. 29811, Jun. 4, 2019]

Article 34-4 (Imposition and Payment of Penalty Surcharges for Manufacturing of Hazardous Drugs) (1) Where the Minister of Food and Drug Safety intends to impose a penalty surcharge under Article 81-2 (1) of the Act, he or she shall give written information of the payment thereof, specifying the type of offense and the amount of penalty surcharge.??

(2) A person informed pursuant to paragraph (1) (hereinafter referred to as "person liable to pay a penalty surcharge") shall pay the penalty surcharge to

the receiving agency designated by the Minister of Food and Drug Safety within 60 days from the date of receiving the information.

(3) The receiving agency upon receipt of the penalty surcharge under paragraph (2) shall issue a receipt to the payer and inform without delay the Minister of Food and Drug Safety of the fact of receiving the penalty surcharge.

(4) Except as provided in paragraphs (1) through (3), matters necessary for imposing and paying penalty surcharges shall be prescribed by Ordinance of the Prime Minister.??

[This Article Newly Inserted by Presidential Decree No. 29811, Jun. 4, 2019]

Article 34-5 (Extension of Deadline for Payment of Penalty Surcharges for Manufacturing of Hazardous Drugs, and Installment Payment) (1) Where a person liable to pay a penalty surcharge is deemed unable to pay the full amount of the penalty surcharge in a lump sum due to any of the following grounds, the Minister of Food and Drug Safety may extend the deadline for payment or permit the penalty surcharge to be paid in installments, upon the application of the person liable to pay the penalty surcharge. In such cases, the Minister of Food and Drug Safety may require such person to offer an asset as security, if deemed necessary:

1. Where the person suffers a serious loss in property due to a natural disaster, calamity, etc.;???
2. Where the business of the person faces a critical crisis due to a deterioration of business conditions;?
3. Where a lump-sum payment of the penalty surcharge is likely to cause severe financial difficulties to the person;
4. Where the person has sustained a net loss consecutively for the three immediately preceding business years as at the time of filing an application for an extension of the payment deadline or for installment payment;?
5. Where the person has a debt exceeding twice the total capital as at the time of filing an application for an extension of the payment deadline or for installment payment;??
6. Where the Minister of Food and Drug Safety deems that there exists any ground corresponding to subparagraphs 1 through 5.

(2) Where a person liable to pay a penalty surcharge intends to extend the deadline for payment of the penalty surcharge or to pay the penalty surcharge in installments under paragraph (1), he or she shall file an application therefor with the Minister of Food and Drug Safety, along with documents evidencing the grounds for the extension of the payment deadline or for the installment payment, within 30 days from the date he or she is informed of the payment of the penalty surcharge.

(3) With respect to the extension of the deadline for payment of a penalty surcharge or the installment payment thereof under paragraph (1), the period extended shall not exceed one year from the date immediately after the payment

deadline; and the interval between individual deadlines for installment payment shall not be longer than three months, and the number of installments shall not exceed three.

(4) Where a person liable to pay a penalty surcharge granted an extension of the payment deadline or permitted to pay such penalty surcharge in installments under paragraph (1) falls under any of the following cases, the Minister of Food and Drug Safety may revoke the decision to extend the deadline for payment or to permit the payment in installments and collect the penalty surcharge in a lump sum:

1. Where the person fails to pay an installment of the penalty surcharge by the deadline for payment;
2. Where the person fails to comply with the order from the Minister of Food and Drug Safety necessary to change security or to preserve security;
3. Where it is deemed impossible to collect the full or remaining amount of the penalty surcharge on the grounds of compulsory execution, commencement of an auction, declaration of bankruptcy, dissolution of a corporation, disposition on delinquent national or local taxes, etc.;??
4. Where it is deemed that the person is able to pay the penalty surcharge in a lump sum because any of the grounds provided in the subparagraphs of paragraph (1) has ceased to exist.?

(5) Except as provided in paragraphs (1) through (4), matters necessary for the extension of the deadlines for payment of penalty surcharges, installment payment thereof, etc. shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Presidential Decree No. 29811, Jun. 4, 2019]

Article 34-6 (Demand for Payment of Penalty Surcharges for Manufacturing of Hazardous Drugs) (1) If a person liable to pay a penalty surcharge fails to pay it by the deadline for payment, the Minister of Food and Drug Safety shall issue a demand for payment within 10 days after the elapse of the deadline for payment (referring to the deadline for payment in a lump sum, where a decision to permit the installment payment of the penalty surcharge is revoked under Article 34-5 (4) after such decision is made under paragraph (1) of that Article) pursuant to Article 81-2 (5) of the Act. ??

(2) In cases of issuing a demand for payment under paragraph (1), the deadline for payment of the penalty surcharge in arrears shall be within 10 days from the date of issuing the demand for payment.

[This Article Newly Inserted by Presidential Decree No. 29811, Jun. 4, 2019]

Article 34-7 (Designation of Professional Training Institution) (1) The Minister of Health and Welfare and the Minister of Food and Drug Safety may designate any of the following institutions or organizations as a professional training institution pursuant to Article 83-2 (2) of the Act (hereinafter referred to as "professional training institution"):

1. The Institute of Drug Safety and Risk Management;
2. Corporations established pursuant to Article 67 of the Act;
3. Universities and colleges where drug-related departments or majors are established, among universities and colleges defined in subparagraph 1 of Article 2 of the Higher Education Act;
4. Other institutions or organizations established to perform duties relevant to drugs or health.

(2) A person who intends to be designated as a professional training institution pursuant to paragraph (1) shall submit to the Minister of Health and Welfare or the Minister of Food and Drug Safety, an application for designation prescribed by Ordinance of the Ministry of Health and Welfare or by Ordinance of the Prime Minister, along with the documents prescribed by Ordinance of the Ministry of Health and Welfare or by Ordinance of the Prime Minister.

(3) The standards for designating a professional training institution shall be as follows:

1. The courses and curricula of education and training shall be appropriate;
2. Appropriate personnel, facilities and equipment for conducting education and training shall be secured;
3. The plan for raising operational funds shall be reasonable.

(4) Where the Minister of Health and Welfare or the Minister of Food and Drug Safety designates a professional training institution, he or she shall issue a certificate of designation prescribed by Ordinance of the Ministry of Health and Welfare or Ordinance of the Prime Minister and publicly announce such fact on the website of the Ministry of Health and Welfare or the Ministry of Food and Drug Safety.

(5) Expenses to be subsidized to a professional training institution pursuant to Article 83-2 (3) of the Act shall be as follows: <Amended by Presidential Decree No. 28081, May 29, 2017>

1. Lecture fees and allowances;
2. Expenses for producing teaching materials and expenses for purchasing tools for practice;
3. Expenses for field practice;
4. Other expenses deemed necessary to train professional personnel.

[This Article Newly Inserted by Presidential Decree No. 26544, Sep. 22, 2015]

Article 34-8 (Functions of the Council for Stable Supply of National Essential Drugs) The Council for Stable Supply of National Essential Drugs (hereinafter referred to as the "Council") under Article 83-3 (3) of the Act shall consult about the following:

1. Designation of national essential drugs;
2. Affairs under the subparagraphs of Article 83-3 (1) of the Act.

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 34-9 (Organization of the Council) (1) The Council shall be comprised of not more than 20 members, including one chairperson.

(2) The Vice Minister of Food and Drug Safety shall serve as the chairperson of the Council.

(3) Members shall be appointed by the head of a relevant agency from among the public officials in general service of the Senior Executive Service of the Ministry of Education, the Ministry of National Defense, the Ministry of the Interior and Safety, the Ministry of Health and Welfare, the Ministry of Employment and Labor, the Ministry of Patriots and Veterans Affairs, the Ministry of Food and Drug Safety, the Office for Government Policy Coordination, and the Nuclear Safety and Security Commission.???<Amended by Presidential Decree No. 28211, Jul. 26, 2017; Presidential Decree No. 28456, Nov. 28, 2017>

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 34-10 (Operation of the Council) (1) The chairperson shall represent the Council and exercise general supervision over its affairs.?

(2) If the chairperson is unable to perform the duties due to any unavoidable reasons, the member pre-designated by the chairperson shall act on behalf of the chairperson.

(3) A regular meeting of the Council shall be held once a year; and a special meeting shall be convened when the chairperson deems it necessary or at the request of at least 1/3 of the members.

(4) Where the chairperson intends to hold a meeting, the chairperson shall inform each member of the date and time, place, and agenda item of the meeting not later than seven days prior to the date of holding the meeting: Provided, That where it is required to urgently hold a meeting or there exists any other unavoidable reason, he or she may give such information not later than the day before the meeting.

(5)?A majority of the members of the Council shall constitute a quorum, and any decision thereof shall require the concurrent vote of a majority of those present.

(6) If necessary for efficient consultation, the chairperson may have a person related to the agenda item or an expert in the relevant field attend and speak at a meeting.

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 34-11 (Working Committee and Subcommittees) (1) A working committee and subcommittees may be established in the Council if necessary to efficiently perform the Council' s affairs.

(2) Matters necessary for the organization and operation of the working committee and subcommittees shall be determined by the Minister of Food and Drug Safety.?

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 34-12 (Executive Secretary) (1) The Council and the working committee,

respectively shall have one executive secretary to deal with the administrative affairs thereof.

(2) An executive secretary shall be designated by the Minister of Food and Drug Safety from among the public officials of the Ministry of Food and Drug Safety.

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 34-13 (Allowances) Allowances, travel expenses, and other necessary expenses may be paid to relevant experts attending meetings of the Council, the working committee, and subcommittees, within budgetary limits.

[This Article Newly Inserted by Presidential Decree No. 28081, May 29, 2017]

Article 35 (Delegation and Entrustment of Affairs) (1) Pursuant to Article 84 (2) of the Act, the Minister of Food and Drug Safety shall delegate the following authority to the head of a regional office of food and drug safety: <Amended by Presidential Decree No. 24479, Mar. 23, 2013; Presidential Decree No. 26544, Sep. 22, 2015; Presidential Decree No. 28820, Apr. 24, 2018; Presidential Decree No. 29811, Jun. 4, 2019>

1. Permission for manufacturing and distribution of items, permission for modification, and permission for renewal; permission for import of each item, permission for modification, and permission for renewal; and acceptance of a notification of import business or a notification of modification, with regard to drugs (limited to the items that need the verification of equivalence of drugs), under Article 31 (2) and (9), 31-5 (3) (including cases applied mutatis mutandis under Article 42 (5) of the Act), or 42 (1) of the Act;
2. Acceptance of a notification of manufacturing and distribution, notification of modification, or notification of renewal, and acceptance of a notification of import of each item, notification of modification, or notification of renewal, with regard to drugs (excluding drug substances determined and publicly notified by the Minister of Food and Drug Safety), under Article 31 (2) and (9), 31-5 (3) (including cases applied mutatis mutandis under Article 42 (5) of the Act), or 42 (1) of the Act;
3. Acceptance of a notification of an import manager or a notification of business closure, etc. by an importer under Article 36 (3) or 40 of the Act applied mutatis mutandis pursuant to Article 42 (5) of the Act;

3-2. Imposition or collection of a penalty surcharge on or from a drug manufacturer, a person who has obtained permission by item, or an importer, and disposition on delinquency under Article 81-2 of the Act;

4. Imposition or collection of administrative fines under Article 98 (1) 4-3 of the Act.

(2) Deleted. <by Presidential Decree No. 24479, Mar. 23, 2013>

(3) The Minister of Health and Welfare shall entrust the following affairs to the Pharmaceutical Association or the Oriental Pharmacy Association pursuant to Article 16 (2) of the Act: <Amended by Presidential Decree No. 20679, Feb. 29,

2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 23459, Dec. 30, 2011>

1. Receipt of notifications of pharmacists or oriental medicine pharmacists under Article 7 of the Act;
2. Training and education of pharmacists or oriental medicine pharmacists under Article 15 of the Act;
3. Review of pharmacists' or oriental medicine pharmacists' ethics under Article 16 (2) of the Act;
4. Investigation and verification of a distribution price indication at pharmacies under subparagraph 10 of Article 56 of the Act.

Article 36 (Special Cases concerning Animal Drugs) In applying Articles 33, 34, 38-2 and 39 to animal drugs, etc. referred to in Article 85 of the Act, the "Minister of Health and Welfare" or the "Minister of Food and Drug Safety" in those Articles shall be construed as "the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries", and "Ordinance of the Prime Minister" or "Ordinance of the Ministry of Health and Welfare" as "Ordinance of the Ministry of Agriculture, Food and Rural Affairs or Ordinance of the Ministry of Oceans and Fisheries". <Amended by Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24479, Mar. 23, 2013; Presidential Decree No. 28456, Nov. 28, 2017>

Article 36-2 (Field Survey Documents for Investigation and Evaluation of Injury from Side Effects of Drugs) "Matters prescribed by Presidential Decree, such as the period and scope of an investigation, persons in charge of investigation, and relevant statutes and regulations" in the latter part of Article 86-6 (3) of the Act means matters under the subparagraphs of Article 32-10.
[This Article Newly Inserted by Presidential Decree No. 27673, Dec. 13, 2016]

Article 37 (Procedures for Paying Monetary Awards) (1) Any supervisory agency or investigative agency upon receipt of a report or accusation of the fact of violating related statutes and regulations under Article 90 of the Act shall inform the head of the competent Si/Gun/Gu of the outline of such violation.
(2) The head of a Si/Gun/Gu informed under paragraph (1) may pay the monetary award within budgetary limits, where an adjudication of the court concerning the relevant case is final and conclusive.
(3) The monetary award under paragraph (2) shall not exceed 10/100 of the amount of a fine sentenced for the said case (where sentenced to imprisonment with labor, the maximum amount of fines under the relevant applied penalty provisions).

Article 38 (Operation of the Korea Orphan and Essential Drug Center) (1) The chairperson of the Korea Orphan and Essential Drug Center under Article 91 of the Act (hereinafter referred to as the "Center") shall submit a business plan and a budget of revenues and expenses for the following year to the Minister of

Food and Drug Safety not later than April 30 of each business year. <Amended by Presidential Decree No. 24479, Mar. 23, 2013; Presidential Decree No. 28081, May 29, 2017>

(2) Where the important matters of the business plan and the budget of revenues and expenses under paragraph (1) are modified, the documents stating the details of and reasons for such modification shall be submitted to the Minister of Food and Drug Safety. <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

(3) Upon receipt of the business plan and the budget of revenues and expenses for the following year under paragraph (1), the Minister of Food and Drug Safety may, if deemed necessary, request the chairperson of the Center to submit data concerning the following matters: <Amended by Presidential Decree No. 24479, Mar. 23, 2013>

1. Matters concerning the projects under the subparagraphs of Article 92 (1) of the Act;
2. Matters concerning the details of financial assistance under Article 92 (2) of the Act.

Article 38-2 (Handling of Sensitive Information and Personally Identifiable Information) The Minister of Health and Welfare (including a person to whom the Minister of Health and Welfare has entrusted his or her affairs pursuant to Article 35), the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a Si/Gun/Gu (where the relevant authority is delegated or entrusted, including a person to whom such authority has been delegated or entrusted), or the national examination administrative agency may handle information on health under Article 23 of the Personal Information Protection Act, information corresponding to criminal history records under subparagraph 2 of Article 18 of the Enforcement Decree of that Act, and data containing resident registration numbers and alien registration numbers prescribed in subparagraph 1 or 4 of Article 19 of that Decree, if inevitable to perform any of the following administrative affairs: <Amended by Presidential Decree No. 24144, Oct. 22, 2012; Presidential Decree No. 24479, Mar. 23, 2013; Presidential Decree No. 26544, Sep. 22, 2015; Presidential Decree No. 28081, May 29, 2017; Presidential Decree No. 28456, Nov. 28, 2017>

1. Administrative affairs concerning registration of a pharmacist or oriental medicine pharmacist license, and issuance and re-issuance thereof under Article 6 of the Act;
2. Administrative affairs concerning notifications by pharmacists or oriental medicine pharmacists under Article 7 of the Act;
3. Administrative affairs concerning national examinations for a pharmacist license or an oriental medicine pharmacist license under Article 8 of the Act;
4. Administrative affairs concerning verification of eligibility requirements for national examinations for a pharmacist license or an oriental medicine pharmacist license under Article 9 of the Act;

5. Administrative affairs concerning registration of establishment of pharmacies or registration of modification thereof under Article 20 of the Act;
6. Administrative affairs concerning notifications of business closure, suspension, or resumption of pharmacies under Article 22 of the Act;
7. Administrative affairs concerning permission for drug manufacturing business, notifications of contract manufacturing and distribution business of drugs, notifications of quasi-drug manufacturing business, and permission for and notifications of modification thereof under Article 31 of the Act;
8. Administrative affairs concerning conditional permission for drug manufacturing business under Article 35 of the Act;
8-2. Administrative affairs concerning notifications of manufacturing managers of drugs, etc. under Article 36 of the Act (including import managers applied mutatis mutandis under Article 42 (5) of the Act);
9. Administrative affairs concerning recall of drugs, etc. under Article 39 of the Act;
10. Administrative affairs concerning notifications of business closure, suspension, and resumption or notifications of replacement of manufacturing managers under Article 40 of the Act;
11. Administrative affairs concerning notifications of manufacturing of pharmacy medications and dispensary medications under Article 41 of the Act;
11-2. Administrative affairs concerning notifications of import business of drugs, etc. or notifications of modification thereof under Article 42 (1) of the Act;
11-3. Administrative affairs concerning registration of a distributor of safe and readily available drugs and registration of modification thereof under Article 44-2 of the Act;
12. Administrative affairs concerning permission, etc. for herb druggists or drug wholesalers under Article 45 of the Act;
13. Administrative affairs concerning directions given under Article 69 of the Act;
14. Administrative affairs concerning administrative dispositions under Articles 70 through 76 and 76-3 of the Act;
15. Administrative affairs concerning hearings under Article 77 of the Act;
16. Administrative affairs concerning appointment of pharmaceutical inspectors under Article 78 of the Act;
17. Administrative affairs concerning revocation of a pharmacist or oriental medicine pharmacist license and suspension of qualifications as a pharmacist or oriental medicine pharmacist under Article 79 of the Act;
18. Administrative affairs concerning renewal of a license, permit, certificate of registration, etc. under Article 80 of the Act;
19. Administrative affairs concerning imposition and collection of penalty surcharges under Article 81 of the Act;
20. Administrative affairs concerning succession to the status of a manufacturer,

etc. under Article 89 of the Act;

21. Administrative affairs concerning payment of a monetary award under Article 90 of the Act;

22. Administrative affairs concerning issuance of a druggist license under Article 5 of the Addenda to the Pharmaceutical Affairs Act (wholly amended by Act No. 8365).

[This Article Newly Inserted by Presidential Decree No. 23488, Jan. 6, 2012]

Article 38-3 (Re-Examination of Regulation) The Minister of Health and Welfare shall examine the appropriateness of the following matters every three years, counting from each base date specified in the following (referring to the period that ends on the day before the base date of every third year) and shall take measures, such as making improvements:

1. Standards for facilities of pharmacies prescribed in Article 22-2: January 1, 2014;
2. Standards for facilities of herb druggists, drug wholesalers, etc., prescribed in Article 31-2: January 1, 2014;
3. Standards for imposition of administrative fines prescribed in Article 39 (1) and attached Table 3: January 1, 2014.

[This Article Newly Inserted by Presidential Decree No. 25050, Dec. 30, 2013]

Article 39 (Imposition and Collection of Administrative Fines) (1) The standards for imposing administrative fines referred to in Article 97-2 (1) of the Act shall be as listed in attached Table 2-3. <Newly Inserted by Presidential Decree No. 26143, Mar. 13, 2015; Presidential Decree No. 29811, Jun. 4, 2019>

(2) The standards for imposing administrative fines referred to in Article 98 (1) of the Act shall be as listed in attached Table 3. <Amended by Presidential Decree No. 26143, Mar. 13, 2015>

(3) Deleted. <by Presidential Decree No. 27673, Dec. 13, 2016>

[This Article Wholly Amended by Presidential Decree No. 21084, Oct. 14, 2008]

ADDENDA <Presidential Decree No. 30170, Oct. 29, 2019>

Article 1 (Enforcement Date)

This Decree shall enter into force on November 1, 2019.

Articles 2 and 3 Omitted.