Regulation on Safety of Pharmaceuticals, etc.

Ordinance of the Prime Minister no. 1848

Partially amended and enforced on Dec 29 2022

Article 1 (Purpose)

The purpose of this regulation is to prescribe matters delegated by the Pharmaceutical Affairs Act and the Enforcement Decree of the Pharmaceutical Affairs Act and matters necessary for their enforcement.

Article 2 (Licensing and Registration of Manufacturing Business, etc.)

(1) A person who intends to obtain approval of manufacturing business of medicinal products or apply for business registration of quasi-drug pursuant to Article 31 (1) and (4) of the Pharmaceutical Affairs Act ("the Act") shall prepare and submit the application form for manufacturing business license of medicinal products (including an electronic document of application form) of Form No. 1 or the application form for manufacturing business register of quasi-drugs (including an electronic document) of Form No. 2, together with the following documents (including an electronic document of registration form), to the Commissioner of the Regional Office of Food and Drug Safety (hereinafter referred to as "the Commissioner of the Regional FDS");

1. Medical certificate issued by a doctor which proves that he/she does not fall under subparagraphs 1 of Article 5 or issued by a medical specialist which proves that he/she does fall under the proviso of the same subparagraph, and issued by a doctor which proves that he/she does not fall under subparagraph 3 of the same Article; and
2. A document which confirms the qualification of the person (hereinafter referred to as "manufacturing supervisor") who supervises the manufacturing of medicinal products or quasi-drugs (hereinafter referred to as "medicinal products, etc.") pursuant to Article 36 of the Act or a certificate of the manufacturing supervisor pursuant to Article 42 (3) of the Act.

(2) The Commissioner of the Regional FDS who receives the application form or registration form pursuant to the paragraph (1) shall confirm the following documents through the common use of administrative information pursuant to Article 36 (1) of the Electronic Government Act: Provided, That in the case of subparagraph 2, if the applicant or the relevant person does not consent to such confirmation, its copy shall be attached.

1. Certificate of corporation registration (in case of corporations);
2. Pharmacist’s license (in case when the manufacturing supervisor is a pharmacist).

(3) A person who intends to register manufacturing business of quasi-drugs pursuant to the paragraph (1)

shall apply for marketing approvals of one or more products belonging to the business at the same time or register a manufacturing and sales business of one or more products at the same time.

(4) Subparagraph 5 of Article 48 shall not apply to the case where a person who has acquired a manufacturing facilities or manufacturing method of medicinal products, etc. through a spin-off or merger of corporation submits documents to prove the fact thereof in order to obtain approval for a new manufacturing business or to register the business with the relevant product in the same facilities and at the same location.

(5) A person who intends to obtain a license or to register a manufacturing business pursuant to the paragraph (1) shall pay a fee announced by the Minister of Ministry of Food and Drug Safety.

Article 3 (Register of Contract Manufacturing and Sales Business of Medicinal Products)

(1) A person who intends to register a contract manufacturing and sales business of medicinal products pursuant to Article 31 (3) of the Act shall submit a contract manufacturing and sales business register application of Form No. 3 (including an electronic document of registration) and attach each document falling under the following subparagraphs (including an electronic document) to the Commissioner of the Regional FDS.

1. Medical certificate issued by a doctor which proves that he/she does not fall under subparagraphs 1 of Article 5 or issued by a medical specialist which proves that he/she does fall under the proviso of the same subparagraph, and issued by a doctor which proves that he/she does not fall under subparagraph 3 of the same Article; and
2. A document which confirms the qualification of a person who performs the duties of post-marketing safety control of medicinal products pursuant to Article 37-3 of the Act (hereinafter referred to as a "safety control manager".)

(2) The Commissioner of the Regional FDS who received the application form pursuant to the paragraph (1) shall confirm each document falling under the following subparagraphs through the common use of administrative information pursuant to Article 36 (1) of the Electronic Government Act: Provided, That in case of subparagraph 2, if the relevant person does not consent to such confirmation, a copy thereof shall be attached.

1. Certificate of corporation registration (in case of corporations);
2. Pharmacist‘s license (in case when the safety control manager is a pharmacist).

(3) A person who intends to register a contract manufacturing and sales business of medicinal products pursuant to the paragraph (1) shall apply for approval of manufacturing and sales of one or more products at the same time.

(4) A person who intends to register a contract manufacturing and sales business shall pay a fee announced by the Minister of Ministry of Food and Drug Safety.

(5) The "clinical trials prescribed by the Ordinance of the Prime Minister” referred to in Article 31 (3) 2 of the Act shall mean clinical trials conducted abroad by a person who intends to report a contract

manufacturing and sales business in accordance with the laws and regulations of the corresponding country after he/she performs the entire or part of the non-clinical trials (including tests on data falling under any of the Subparagraphs 1 to 3 of Article 9) domestically. <Newly established, Sept. 25, 2015>

(6) In Article 31 (3) 3 of the Act, “drugs prescribed by the Ordinance of the Prime Minister” refer to orphan drugs (medicines that shall be imported urgently because there are no suitable alternative drugs, and are designated by the Minister of Ministry of Food and Drug Safety, hereinafter the same shall apply) and refer to drugs that require to be or have been re-reviewed according to Article 22 (1)<Newly established on Oct 25, 2018., July 21, 2022>

Article 4 (Application for Marketing approval of Manufacture, Sales and Importation)

(1) A person who intends to obtain approval for manufacturing, sales and importation of pharmaceuticals, etc. pursuant to Article 31 (2) through (4) of the Act or Article 42 (1) of the Act shall attach the documents in each of the following subparagraphs and submit it to the Minister of Ministry of Food and Drug Safety (in case of manufacturing, sales, and importation of pharmaceuticals that require proof of equivalence of pharmaceuticals and manufacturing, sales and importation of quasi-drugs that do not need to be submitted in accordance with proviso besides subparagraph 1, it shall be submitted to the head of the regional office). <Amended on May 9, 2014, Aug 21, 2014, Mar 13, 2015, Sep 25, 2015, Oct 28, 2016, Jan 4, 2017, Oct 25, 2018, Oct 14, 2020, Mar 8, 2021, Sep 10, 2021, Jan 20, 2022, Jul 21, 2022, Dec 29, 2022>

1. Information on safety and efficacy pursuant to Article 9: Provided, That documents of the products which are not biological preparations, gene recombination products, cell culture products, cell therapy products, gene therapy products and other preparations similar thereto (hereinafter referred to as "biological products, etc.") and which fall under any of the following items and are manufactured at the same production facility manufacturing already approved products in Korea with final bulk product thereof being identical to the approved product, shall not be required to be submitted.
   (a) Products listed in the Pharmacopoeia of the Republic of Korea (hereinafter referred to as the "KP") pursuant to Article 51 (1) of the Act;
   (b) Products listed in official compendia or pharmaceutical references recognized by the Minister of Ministry of Food and Drug Safety;
   (c) Medicinal products that are not listed in KP, but listed in the criteria for herbal medicine (hereinafter referred to as "Korean traditional (herbal) medicine Pharmacopoeia")
   (d) Products meeting the standard manufacturing specifications which includes which includes kinds of ingredients, specifications, strength, formula, and others standardized and announced by the Minister of Ministry of Food and Drug Safety;
   (e) Products of which specifications and testing methods are specifically announced by the Minister of Ministry of Food and Drug Safety; or

(f) Other products which are approved by the Minister of Ministry of Food and Drug Safety that the submission of data is not necessary.

2. Information on specifications and testing methods pursuant to Article 10: Provided, That data of a product shall not be submitted when the product falls under any of the following subparagraphs:

   A. Items falling under subparagraph 1 (a) through (c) and (e) among over-the-counter drugs

   B.Items falling under subparagraph 1 (a) through (c) and e (e) among drug substances

   C. Items falling under subparagraph 1 (a), (b) and (e) among quasi-drugs

3. In case of products falling under any of the following items, date of bioequivalence test results or comparative clinical trial results for the product shall be required: Provided, That in case of the product announced by the Minister of Ministry of Food and Drug Safety, data of test or demonstration such as comparative dissolution test in which no living body is used shall be required to be submitted announced by the Minister of Ministry of Food and Drug Safety.

   (a) Prescription drugs which have been approved for manufacture, sales or importation after January 1st, 1989 and fall under the category of new drugs (including those products which have a different dosage form with the same administration route);

   (b) Prescription drugs which are tablets, capsules, suppositories, powders, granules, ophthalmics, ear drops, inhalants for application to the lungs, external preparations having the same ingredients as those already approved for manufacturing, sales, and importation except for products falling under item a: Provided, That those medicinal products shall be commercial drugs, expensive drugs, single-compound drugs, or drugs which require equivalence and shall be the products that are announced by the Minister of Ministry of Food and Drug Safety.

   (c) Prescription drugs that have the same ingredients as items that have already obtained approval for manufacturing, sales, or import among prescription drugs, excluding items falling under Items A or B.

4. For imported medicinal products, the documents falling under the following subparagraphs concerning the manufacture and sales of products. In such cases, detailed matters concerning the requirement, etc. of documents to be attached shall be as announced by the Minister of Ministry of Food and Drug Safety.

   (a) A certificate of pharmaceutical product which verifies that the product is manufactured in compliance with the laws and regulations of the relevant producing country, issued by the government or public agency of the country;

   (b) A certificate of free sales which verifies that the product is for sale in compliance with the laws and regulations of the country where the product has been approved and registered, issued by the government or public agency of the country.

5. In case when intending to obtain approval of single-compound drugs among non-prescription drugs or prescription drugs (excluding products under Subparagraph 3), having the same ingredient as tablets, capsules or suppositories which have been already approved for manufacture, sales and importation, data such as comparative dissolution test data, etc. as announced by the Minister of Ministry of Food and Drug Safety.
6. Evaluation data pursuant to each sub-paragraph:
   (a) In the case of finished drugs and quasi-drugs [applicable only to solid formulations for internal use, liquid formulations for internal use, and ointments for external skin and cataplasma drugs that meet the standard manufacturing criteria for drugs notified by the Minister of Ministry of Food and Drug Safety], data necessary for evaluating whether it meets GMP in Annex 1;
   (b) In the drug substances [Among drug substances, there are no herbal medicines and pharmacological activity (actions on the human body in terms of pharmacological action) and other products used for products that are not directly applied to the human body are excluded], data necessary for evaluation of compliance with GMP for drug substance in Annex 1-2.
   (c) In the case of biological products, etc. [blood products (hereinafter referred to as “blood products”) pursuant to subparagraph 8 of Article 2 of the 「Blood Management Act」, Data necessary for evaluation of compliance with GMP in Annex 1 and GMP for drug substances in Annex 1-2 and GMP for biologics in Annex 3;
   (d) In case of radiopharmaceuticals, data required for GMP inspection under Good Manufacturing Practice for Medicinal Products in Annex 1, Good Manufacturing Practice for Drug Substances in Annex 1-2 and Good Manufacturing Practice for Radiopharmaceuticals of Annex 3-2;
   (e) In case of high-pressure gases for medical use(An item designated and notified by the Minister of Ministry of Food and Drug Safety among disinfectants which are directly used to the human body is excluded) , Data necessary for evaluation of compliance with GMP in Annex 1 and GMP for drug substances in Annex 1-2 and GMP High Pressure Gases for Medical Use in Annex 3-3;
   (f) In case of herbal substances, data required for GMP inspection under Good Manufacturing Practice for Herbal Substances of Annex 2: Provided, That in case of applying for marketing approval for manufacturing, sales and importation of two or more products at the same time, data regarding only one product thereof may be submitted.
   (g) In the case of blood products, data necessary to evaluate whether they meet GMP for blood product in Annex 3-4
7. In case of products including drug substances of a new drug or drug substances which are determined and announced by the Minister of Ministry of Food and Drug Safety (hereinafter referred to as "API subject to registration") which may be registered pursuant to Article 31-2 (1) of the Act, data falling under the following items regarding drug substances shall be submitted.

However, in the case of drug substances already registered in accordance with Article 15 (1), the data submitted at the time of registration in accordance with the same paragraph shall not be submitted.

A. Name, address and responsible persons of the manufacturing site;

B. Information on storage methods and expiry period;

C. Information as specified in Article 15 (1).

8. Data concerning the name and address of the manufacturer of drug substances which are announced by the Minister of Ministry of Food and Drug Safety.
9. A written contract manufacturing agreement with the name and address of the contract acceptor on it for medicinal products manufactured under contract pursuant to Article 31 (2) and (3) of the Act.
10. A patent confirmation document provided in the Form No. 5, explanatory statement, supporting data in case when applying for marketing approval for manufacturing, sales and importation of medicinal products based on safety and efficacy data of medicinal products of which the patent rights for medicinal products (hereinafter referred to as “patent rights for medicinal products”) are registered in the patent list (hereinafter referred to as the “patent list”) of medicinal products (hereinafter referred to as "registered drugs") pursuant to Article 50-2 (4) of the Act (including the case to which Article 42 (5) of the Act applies mutatis mutandis).
11. For drugs prescribed by the Minister of Ministry of Food and Drug Safety, such as new drugs and orphan drugs, a comprehensive drug safety management plan (hereinafter referred to as “risk management”) including risk mitigation measures prescribed by the Minister of Ministry of Food and Drug Safety, such as instruction manuals for patients and measures to ensure safe use.
12. When applying for products approval for manufacturing and sales pursuant to Article 31 (3) 2 of the Act or the subparagraph 3, document which proves that they are medicinal products under the same subparagraph respectively.

(2) (#)Notwithstanding the paragraph (1), some data may not be submitted as described in the following sub-paragraphs if any of the following is applicable. <Revised on Oct. 10, 2014, June 30, 2016>

1. If the notification of the result from a prior review under Article 41 (3) stating suitability of data corresponding to Subparagraph 1 or 2 of Paragraph (1) is submitted: data referred to in Subparagraph 1 or 2 of Paragraph (1);
2. If a manufacturing site which manufactures the product (excluding new drugs, biological products, injections, transplants and others as announced by the Minister of Ministry of Food and Drug Safety) for the submission of marketing approval for manufacturing and sales holds the Certificate of GMP compliance under Article 48-2(case falling under subparagraph 3 is excluded) data referred to in Subparagraph 6 of Paragraph (1);
3. If contracting the manufacture of the product for which application has been filed for approval of

manufacturing and sales to a manufacturing site of a marketing authorization holder of the same product so that the entire manufacturing process would be the same as the product of the corresponding manufacturing site: data referred to in Subparagraph 6 of Paragraph (1); Provided, in the case of b, performance data more than 1 batch shall be submitted;

A. In cases where all manufacturing processes are the same as those for which approval for manufacturing and sales has been obtained or for which item notification has been made (limited to over the counter drugs, drug substances and quasi-drugs)

B. In cases where the manufacturing process, manufacturing facilities, manufacturing units, materials and types of containers and packaging that come into direct contact with medicines are all the same as those for which approval for manufacturing and sales has been obtained or item notification has been made (limited to prescription drugs)

4. If complying with the standards notified by Minister of Ministry of Food and Drug Safety: data referred to in Subparagraph 4 of Paragraph (1).
5. In the case of essential national drugs for which there are no substitutes for drugs that the Minister of Ministry of Food and Drug Safety deems to have sufficiently secured safety and efficacy through consultation with the Central Pharmaceutical Affairs Council pursuant to Article 18 (1) of the Act: Data determined and notified by the Minister of Ministry of Food and Drug Safety among the data corresponding to Paragraph 1 Subparagraph 1

(3) Notwithstanding the paragraph (1), a transferee of manufacturing facilities or manufacturing procedures of medicinal products, etc. by spin-off or merger who intends to obtain the approval of product transferred may submit the transfer contract concerning manufacturing facilities and manufacturing methods, etc. instead of one of the documents under each provision of the paragraph (1).

(4) In case of approval pursuant to the paragraph (3), conditions may be added which are equivalent to those added to marketing approval for manufacturing, sales and importation applying to a transferer.

(5) When deemed necessary for marketing approval for manufacturing, sales and importation of medicinal products, etc. pursuant to Article 31 (2) through (4) of the Act or Article 42 (1) of the Act, the Minister of Ministry of Food and Drug Safety may listen to the opinions of National institute of Food and Drug Safety Evaluation or seek an advice from Central Pharmaceutical Affairs Council pursuant to Article 18 (1) of the Act.

(6) A person who applies for approval pursuant to the paragraph (1) shall pay a fee announced by the Minister of Ministry of Food and Drug Safety (including expenses needed for site inspection in foreign countries, if any).

[Enforcement date: Oct. 29, 2018] Parts regarding powders・granules in the revised regulation of the subparagraph 3 of the Article 4(1)

[Enforcement date: Oct. 29, 2019] Parts regarding opthalmics・ear drops·inhalant for application or

external preparations

[Enforcement date] Amended provisions of Article 4 (1) 3 (c): The date according to the classification of each of the following items

A. Prescription drugs that are oral preparations: the day after 1 year and 6 months which have elapsed since promulgation

B. Prescription drugs that are aseptic preparations: the date on which 2 years which have elapsed since promulgation

C. Prescription drugs other than Items A and B: The date on which 3 years which have elapsed since promulgation

Article 5 (Notification of Manufacture, Sales and Importation)

(1) Medicinal products, etc. of any of following subparagraphs shall be reported pursuant to Article 31 (2) and (4) or Article 42 (1) of the Act. However, products of which marketing approval and notification of manufacture, sales and importation shall be restricted pursuant to Article 11, products of which safety and efficacy data shall be submitted pursuant to Article 4 (1) subparagraph 1, biological products, etc., radiopharmaceuticals, and registered drugs shall be excluded.

1. Products listed in the KP or official compendia which are approved by the Minister of Ministry of Food and Drug Safety or the Korean pharmaceutical codex. However, medicinal products not approved in Korea shall be excluded.
2. Products that are listed in the Korean traditional (herbal) medicine Pharmacopoeia;
3. Products meeting the standard manufacturing specifications which includes kinds of ingredients, specifications, strength, formula, and others standardized and announced by the Minister of Ministry of Food and Drug Safety;
4. Products of which specifications and testing methods are announced by the Minister of Ministry of Food and Drug Safety;
5. Other products announced by the Minister of Ministry of Food and Drug Safety as subject to registration.

(2) A person who intends to register manufacture, sales and importation of medicinal products, etc. pursuant to the paragraph (1) shall submit the notification form of manufacture, sales and importation of medicinal products, etc. of Form No. 6 (including an electronic document of registration) together with data falling under each of the following subparagraphs (including electronic documents) to the Commissioner of the Regional FDS. <Revised on Aug. 21, 2014>

1. Data proving that the product is subject to register under paragraph (1);
2. Information as prescribed in Article 4 (1) subparagraph 2 (medicinal products among those falling under subparagraph 3 of paragraph (1), limiting to the cases of products determined not

to meet GMP requirements of Annex 1 pursuant to subparagraph 5 of Article 48 and products under subparagraph 5 of paragraph (1) of this Article);

3. Information as prescribed in Article 4 (1) 3 and 5 (limiting to the cases of medicinal products deemed necessary to prove drug equivalence by the Minister of Ministry of Food and Drug Safety in accordance with Article 27 (2) subparagraph 1 of the Act);
4. Data under Article 4 (1) 4. Provided, it may not be submitted if it meets the standards determined and notified by the Minister of Ministry of Food and Drug Safety;
5. Information as prescribed in Article 4 (1) subparagraph 6;
6. Information as prescribed in Article 4 (1) 7 through 9.

(3) A transferee of manufacturing facilities or manufacturing procedures of medicinal products, etc. by spin-off or merger intends to report the transferred products may submit the transfer contract in lieu of attached documents or data pursuant to paragraph (2). However, data pursuant Article 4 (1) 6 shall be submitted if evaluation of the GMP implementation status is necessary in accordance with Annex 1, Annex 1-2, Annex 2 or Annex 3-3. <Revised on Aug. 21, 2014>

(4) A person who intends to register pursuant to paragraph (2) shall pay a fee (including overseas on-site inspection expenses if it is necessary to carry out) as announced by the Minister of Ministry of Food and Drug Safety.

Article 6 (Establishment of Business Offices)

(1) A person who has obtained marketing approval of manufacture and sales of medicinal products or applied for register manufacture, sales and importation of medicinal products (hereinafter referred to as a "marketing authorization holder") in accordance with Article 31 (5) of the Act shall have a pharmacist or an oriental pharmacist (hereinafter referred to as the "business office manager") responsible for management of each business office at every business office.

(2) The business office shall have a warehouse: Provided, That a marketing authorization holder of medicinal gases shall meet the requirements for facilities needed for sale of medicinal gases in accordance with Article 4 (4) of the High-Pressure Gas Safety Control Act and a marketing authorization holder of radiopharmaceuticals shall meet the requirements for facilities needed for sale of radioactive isotopes in accordance with Article 55 (1) of the Nuclear Energy Safety Act.

(3) The warehouse at the business office under the paragraph (2) shall have the following facilities: Provided, that the facilities falling under subparagraphs 4 to 7 shall apply to business offices that handle the relevant medicinal products and the facility falling under the subparagraph 8 shall apply to business offices where adulterated or returned medicinal products are held.

1. Facilities for storage at cold temperature and protection from sunlight;
2. Facilities for protection from rodents, insects and others;
3. Facilities maintaining temperature and humidity levels to prevent deterioration of medicinal products;

4. Facilities for dedicated storage of biological products (including shipping containers);
5. Facilities for storage of narcotics and psychotropic drugs;
6. Facilities for storage of flammable or explosive medicinal products;
7. In case of medicinal products requiring special storage methods, facilities for maintenance of such storage conditions; and
8. Facilities for storage of adulterated or returned medicinal products.

(4) Provisions regarding medicinal products wholesalers referred to in Article 32 of the Enforcement Decree of Pharmaceutical Affairs Act (hereinafter referred to as the "Decree"), Article 62 of this regulation and Article 44 of the Enforcement Regulation of Pharmaceutical Affairs Act shall apply mutatis mutandis to matters to be observed by a marketing authorization holder to establish the distribution system of medicinal products and maintain the sales order.

Article 7 (Subject to be Excluded from Manufacturing Business and Marketing Approval or Notification for Manufacturing, Sales and Importation)

Pursuant to Article 31 (6) of the Act, medicinal products, etc. falling under any of the following subparagraphs shall be subjects which are excluded from manufacturing business and marketing approval for manufacturing, sales and importation and registration thereof pursuant to Article 31 (1) through (4) of the Act.

1. Investigational products, etc. approved for clinical trial plan pursuant to Article 24 (1);
2. Drug substances or comparator (including placebo) to be used for clinical trials purpose;
3. Medicinal products, etc. to be used to obtain marketing approval for manufacturing, sales and importation of medicinal products, etc. or register thereon.

Article 8 (Application for Change of Approved Matters, etc.)

(1) When a manufacturer, an importer or a contract manufacturing and sales business person of medicinal products, etc. intends to change approved or registered matters pursuant to Article 31 (9) or Article 42 of the Act, he/she shall submit application form or a registration form (including an electronic document of registration form) to the Minister of Ministry of Food and Drug Safety (or to the Commissioner of the Regional FDS in case when intending to change the approval and registration of manufacturing business of medicinal products, etc., the registration on a contract manufacturing and sales business, the report on an importing business, the marketing approval of manufacture, sales and importation of medicinal products for which verification of medicinal product equivalence is deemed necessary, the marketing approval of manufacture, sales and importation of quasi-drugs, etc. which are not subject to be examined, and the registration on manufacture, sales and importation of medicinal products, etc.) with the certificates of approval or registration, explanatory statement of changes (including and electronic document) and supporting documents thereof (i.e., documents falling under each subparagraph of Article 4 (1) and including

an electronic document) according to each of following subparagraphs. <Revised on Sep. 25, 2015>

1. Change of a manufacturing business: a change registration form for quasi-drug manufacturing business provided in the Form No. 2 or a change approval application form for manufacturing business of medicinal products, etc. provided in the Form No. 7;
2. Change of a contract manufacturing and sales business: a change registration form for contract manufacturing and sales business provided in Form No. 3;

2.2. Change of an importing business: a change registration form for an importing business of medicinal products, etc. provided in Form No. 7-2;

3. Change of a product: a change registration form for registration of manufacture, sales and importation of medicinal products, etc. provided in the Form No. 6 or a change application form for approval of manufacture, sales and importation of medicinal products, etc. provided in the Form No. 8.

(2) When a representative of a corporation is to be changed in paragraph (1), medical certificate issued by a doctor which proves that the representative does not fall under subparagraph 1 of Article 5 of the Act or does fall under the proviso of the same subparagraph and which proves that he/she does not fall under subparagraph 3 of the same Article shall be attached to the change approval application or the change report forms.

(3) Notwithstanding the provision of paragraph (1), in case when falling under any of the following subparagraphs and the Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS orders the change of products when deemed necessary to change already approved or registered matters of manufacture, sales and importation after evaluation within certain period pursuant to the partial proviso other than every items of Article 76 (1) of the Act, it shall be considered that the Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS approves the changes or accepts the change reports: <Revised on Aug. 21, 2014, Sep. 25, 2015>

1. Renewal of marketing approval for manufacturing, sales and importation of medicinal products pursuant to Article 31-5 of the Act (including cases applicable mutatis mutandis in Article 42 (5) of the Act);
2. Re-examination of new drugs, etc. pursuant to Article 32 of the Act;
3. Re-evaluation of medicinal products pursuant to Article 33 of the Act;
4. Review of safety and efficacy data submitted under Article 4, this Article and Article 41;
5. Reporting on safety information pursuant to subparagraph 3 of Article 48;

5-2. Evaluation of safety and effectiveness according to the implementation of the risk management plan under subparagraph 20 of Article 48

6. Evaluation on safety and efficacy and effect, etc. to provide information on appropriate use of medicinal products;

7. Revised on of the Pharmacopoeia of Republic of Korea and specifications of medicinal products, etc. pursuant to Article 52 of the Act;
8. Review of safety and efficacy data from studies conducted because it was deemed necessary to assure public health, including classification of medicinal products.

(4) Notwithstanding the provision of paragraph (1), for minor matters prescribed and announced by the Minister of Food and Drug Safety such as the change of color, etc. which does not affect the quality, a document (including an electronic document) on which the contents of change are written shall be submitted to the Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS pursuant to those prescribed and announced by the Minister of Ministry of Food and Drug Safety. In this case, change approval or change report is regarded granted or made pursuant to Article 31 (9) of the Act or Article 42 of the Act. <Revised on Oct. 28, 2016>

(5) The Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS who receives an application or report form or an change application or report form pursuant to paragraph (1) shall check a copy of the certificate of corporation register (applicable to corporations only) through common use of administrative information pursuant to Article 36 (1) of the Electronic Government Act.

(6) When the Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS grants change approval or receives change report pursuant to paragraph (1) or receive status succession report pursuant to Article 103 (1), the changed matter shall be written on the relevant approval or register form, certificate of approval or certificate of register pursuant to Article 13(each electronic document is included. Hereinafter the same shall apply). <Amended 2021. 3. 8.>.

(7) A person who intends to apply or register pursuant to paragraph (1) shall pay a fee (On-site inspection in foreign countries expense is included) as announced by the Minister of Ministry of Food and Drug Safety: Provided, That this shall not apply to case when the location is changed by administrative district reorganization.<Amended on Oct 14, 2020>.

(8) When intending to change the location of a manufacturing site or business office pursuant to paragraph (1), subparagraph 5 of Article 48 shall apply mutatis mutandis.

Article 9 (Data regarding Safety and Efficacy)

Data required to be submitted regarding safety and efficacy by a person who intends to obtain marketing approval for manufacturing, sales and importation or for change of product of medicinal products, etc. or intends to file a notification on manufacture, sales and importation or on change of notification of medicinal products, etc. shall be data falling under each of the following subparagraphs (including an electronic document). In such case, matters to be required to control non-clinical trials conducted to obtain information and fill out required documents regarding products required to submit data thereof, means for preparation of documents, specific information on requirements for every document, the scope of exemptions and etc. and toxicology and pharmacology, etc. shall be followed as prescribed and announced

by the Minister of Ministry of Food and Drug Safety.

1. Information on origin or discovery and pharmaceutical development;
2. Information on structural characterization and physicochemical properties;
3. Information on stability;
4. Information on toxicology;
5. Information on pharmacology;
6. Information on clinical trials;
7. Information on use in foreign countries; and
8. Information on review in comparison with similar products in Korea and characteristics of the relevant medicinal products.

Article 10 (Information on Specifications & Test Methods)

(1) A person who applies for marketing approval of manufacture, sales and importation of medicinal products, etc. or amendment thereof pursuant to Article 31 (11) or Article 42 (6) of the Act shall submit the information on specifications and test methods for production and quality control of the relevant medicinal product. The types of documents, methods for preparation of documents, requirements for individual documents and other detailed matters shall be announced by the Minister of Ministry of Food and Drug Safety. <Revised on Sep. 25, 2015>

(2) A person who intends to submit the information on specifications and test methods under the paragraph (1) shall also submit to the Minister of Ministry of Food and Drug Safety the relevant medicinal product subject to review (limiting to cases where the Minister of Food and Drug Safety considers that submission of products is especially needed for quality examinations.

Article 11 (Subjects with Restriction on Marketing Approval or Notification of Manufacture, Sales and Importation of Medicinal Products, etc.)

(1) Medicinal products, etc. with restriction on marketing approval or notification of manufacture, sales and importation pursuant to Article 31 (11) or Article 42 (6) of the Act shall be as follows: <Revised on May 9, 2014, Sep. 25, 2015>

1. Products falling under stimulants and excitants;
2. Composite medication containing vitamin and sexual hormone preparations;
3. Deleted <Dec. 13, 2017>
4. Products falling under a form of medicinal product which is non-processed herbal medicines mixed after being cut or crushed;
5. Products same as those of which marketing approval has been revoked and it has not been a year after the date of such revocation;
6. Products which have been notified as targets of medicinal product re-evaluation by the Minister of Ministry of Food and Drug Safety pursuant to Article 33 of the Act and the

result thereof has not been announced: Provided, That products falling under any of the following items shall be excluded.

(a) Products of which necessary data needed for re-evaluation have been submitted pursuant to Article 33 of the Act;

(b) Products of which the relevant manufacturing facilities, process, etc. are transferred and acquired according to spin-off, merger, or etc. of corporation;

(c) Products which are requested by the Minister of Health and Welfare due to stringent necessity such as national vaccination business, preventive actions, etc.

7. Products containing ingredients which may inspire disgust or stimulate the desire of people so that the misuse or the abuse thereof is expected;

8. Products containing ingredients which are notified as having safety and efficacy problem by the Minister of Ministry of Food and Drug Safety. However, special products which will not be directly applied to human body shall be excluded.

9. Products of which marketing approval or notification of manufacture, sales and importation deemed to be necessary by the Minister of Ministry of Food and Drug Safety recognizes while considering public interest or international agreement, such as plasma derivatives, gene therapy drugs, etc. However, products falling under any of the following items shall be excluded:

(a) Plasma derivatives of which marketing approval of manufacture, sales and importation is applied by the Korean Red Cross (KRC) established in accordance with the Organization of the Korean National Red Cross Act;

(b) Plasma derivatives of which marketing approval of manufacture, sales and importation is applied by the KRC or other approved manufacturers which conclude ingredient supply contracts with blood banks licensed pursuant to Article 6 of the Blood Management Act;

(c) Plasma derivatives and gene therapy products which are separately designated by the Minister of Ministry of Food and Drug Safety.

10. Products which are subdivisions of medicinal products falling under any of the following subparagraphs:

(a) Medicinal products under national batch release pursuant to Article 53 (1) of the Act;

(b) Antibiotic substances and preparations thereof; or

(c) Radiopharmaceuticals.

11. Products using or containing ingredients which could carry diseases such as bovine spongiform encephalopathy that may harm public health and are designated by the Minister of Ministry of Food and Drug Safety.

(2) Product name of medicinal products, etc. falling under any of the following subparagraphs pursuant to Article 31 (11) and Article 42 (6) of the Act shall not be obtained marketing

approval or registered for manufacture, sales and importation. <Revised on Sep. 25, 2015>

1. A name which is inappropriate to be used as the name of medicinal products, etc., and is likely to be misunderstood as other product or is exaggerated than the product really is;
2. A name which directly indicates diseases(Indication: Refers to applicable diseases or symptoms. Hereinafter the same shall apply) for which medicinal product is efficacious or its efficacy (except for special products such as diagnostic reagents);
3. A name indicates only a part of ingredients and the medicinal product is a complex of two or more active pharmaceutical ingredients;
4. A name of medicinal products, etc. which is not attached with relevant documentary evidence concerning use permission of trademark of the holder of trademark right in cases where a foreign brand is supposed to be used;
5. A name which is likely to be mistaken as a sort of ginseng established by the Ginseng Industry Act and the Food Sanitation Act.

(3) Notwithstanding each subparagraph of paragraph (1) (except subparagraph 8) and paragraph (2), the provisions shall not to product applied for approval or registration of manufacture, sales and importation with the purpose of exportation, military supply or government supply.

Article 12 (Criteria of Approval, etc.) Details concerning criteria, condition, management, etc. of manufacturing business, contract manufacturing and sales business of medicinal products, etc., and marketing approval and registration of manufacture, sales and importation of medicinal products, etc. and other than matters specified in Articles 2 to 5, 7, 8, 11, 39, 39-2 and 40 shall be determined and notified by the Minister of Ministry of Food and Drug Safety<Revised on Sep. 25, 2015, July 21,2022>.

Article 12-2 (Notice of Safety and Efficacy Review Results)

(1) A person who submits the application for marketing approval of manufacture, sales and importation of new drugs and others in accordance with Article 4 may request the Minister of Ministry of Food and Drug Safety to conduct the safety and efficacy review in advance, in order to apply for decision of medical treatment benefit under Article 10-2 of the Rule of Health Care Benefit under National Health Insurance.

(2) If the request of paragraph (1) is deemed appropriate, the Minister of Ministry of Food and Drug Safety shall conduct the safety and efficacy review and notify the applicant of review results.

(3) If necessary, the Minister of Ministry of Food and Drug Safety may provide the President of Health Insurance Review & Assessment Service under Article 62 of the National Health Insurance Act with the safety and efficacy review results notification provided to the applicant under paragraph (2) and the relevant supporting documents. [Newly established, Aug. 21, 2014]

Article 13 (Approval and Registration Log and Certificate of Approval and Registration, etc.)

(1) When manufacturing business license of medicinal products or marketing approval of manufacture and sale of medicinal product, etc. pursuant to Article 2 or 4 is granted, the Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS shall put each of the following matters on the register and issue a certificate of license/approval provided in the Form No. 9 or No. 10.

1. For licensing of manufacturing business;
   (a) License number and date of license;
   (b) Name and resident registration number of manufacturer (name and resident registration number of a representative for corporation);
   (c) Name and address of manufacturing site;
   (d) Name, resident registration number and qualification of manufacturing supervisor (in cases where the manufacturer is in charge of manufacturing, the fact and his qualification);
   (e) Name, qualification and resident registration number of safety control manager pursuant to Article 37-3 (2) of the Act (applicable to the case when the safety control manager is mandatory pursuant to Article 46 (1) only).
2. For marketing approval of manufacturing and sales
   (a) Approval number and date of approval;
   (b) Name of product.

(2) When manufacturing business register of quasi-drugs pursuant to Article 2, contract manufacturing and sales business register of medicinal products pursuant to Article 3, importing business of medicinal products pursuant to Article 56-2, or notification of manufacture, sales and importation of medicinal products pursuant to Article 5 is accepted, the Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS shall put each of the following matters on the register and issue a certificate of register provided in the Form No. 11 for manufacturing business of quasi-drugs for quasi-drugs manufacturing business, certificate of register provided in the Form No. 12 for contract manufacturing and sales business of medicinal products and certificate of notification of manufacture, sales and importation provided in the Form No. 13 for notification of manufacture, sales and importation of medicinal products, etc. <Revised on Sep. 25, 2015>

1. For manufacturing business register of quasi-drugs;
   (a) Register acceptance number and date of acceptance;
   (b) Name and resident registration number of manufacturer (name and resident registration number of a representative for corporation);
   (c) Name and address of manufacturing site;
   (d) Name, resident registration number and qualification of manufacturing supervisor (in cases where the manufacturer is in charge of manufacturing, the fact and his qualification).

2. For contract manufacturing and sales business register of medicinal products;
   (a) Register acceptance number and date of acceptance;
   (b) Name and resident registration number of contract manufacturing and sales business person (name and resident registration number of a representative for corporation);
   (c) Name and address of contract manufacturing and sales business office;
   (d) Name, qualification and resident registration number of safety control manager.

2.2 For importing business register of medicinal products, etc.:
   (a) Register acceptance number and date of acceptance;
   (b) Name and resident registration number of the importer (in the case of a corporation, the name and resident registration number of the representative);
   (c) Name, resident registration number and qualification of import supervisor (in cases where the importer is in charge of manufacturing, the fact and his qualification);
   (d) Name, qualification and resident registration number of safety control manager.

3. For notification of manufacture, sales and importation;
   (a) Register acceptance number and date of acceptance;
   (b) Name of product.

(3) When a conditional license/approval pursuant to Article 39 is granted, the Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS shall put matters falling under each subparagraph of the paragraph (1) on the register and issue a certificate of conditional license/approval for pharmaceutical facilities(each certificate in electronic form is included. Hereinafter the same shall apply) provided in the Form No. 14 or No. 15.(Amended on Mar 8, 2021, Jul 21, 2022>.

(4) When the fulfillment of condition pursuant to Article 40 (2) is confirmed, the Minister of Food and Drug Safety or the Commissioner of the Regional FDS shall reissue a relevant certificate of license/approval of paragraph (1), in lieu of certificate of conditional license/approval.

(5) If a person who has obtained the certificate of license or registration pursuant to Paragraphs (1) and (2) intends to apply for approval of manufacturing business of veterinary drugs, approval or registration of pharmaceuticals pursuant to the Enforcement Rules for the Control of Veterinary Drugs, etc. in order to manufacture and market the identical products as the licensed or notified for animal use, he/she may request the Minister of Ministry of Food and Drug Safety to provide the entire or some of data submitted pursuant to Articles 4 and 5 to the Commissioner of the Animal and Plant Quarantine Agency and the Director of the National Institute of Fisheries Science. <Newly established, March 30, 2018>

(6) The Minister of Ministry of Food and Drug Safety who has received the request to provide data pursuant to Paragraph (5) may provide the relevant data to the Commissioner of Animal and Plan Quarantine Agency and the Director of the National Fisheries Science. <Newly established, March 30, 2018>

Article 14 (Confirmation of Approved Matters of Medicinal Products, etc.)

(1) A person who intends to receive confirmation or certification of marketing approval or registration of medicinal products or API drug master file pursuant to Article 31, Article 31-2 and Article 42 of the Act shall submit an application of confirmation or certification (including an electronic document and a translated document for foreign language where applicable) to the Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS. <Revised on Aug. 21, 2014>

(2) A person who intends to receive confirmation or certification shall pay a fee as announced by the Minister of Ministry of Food and Drug Safety.

Article 15 (Registration of Drug Substances (Drug Master File))(1) A person who intends to file a Drug Master File (DMF) pursuant to Article 31-2 (1) or Article 42 (4) of the Act shall submit a Drug Master File application form provided in the Form No. 16 (including an electronic document) together with data of each of the following subparagraphs (including electronic documents) to the Minister of Ministry of Food and Drug Safety. In such cases where data protection is particularly necessary, supplier of drug substances may submit any of the following subparagraphs directly to the Minister of Ministry of Food and Drug Safety: <Revised on Aug. 21, 2014, Oct. 28, 2016>

1. Data concerning the manufacturing site of drug substances as shown below:
   A. Data concerning facilities pursuant to Article 31 (1) of the Act;
   B. Data proving compliance with GMP for drug substances in Annex 1-2 for each item (standards at or above the same level is included) or manufacturing certificate under Article 4 (1) 4 (a);
2. Data concerning composition, names and manufacturing methods of drug substances as shown below:
   A. Data on physicochemical properties and stability;
   B. Data on manufacturing methods, packaging, container, handling precautions, etc.;
   C. Data on test reports, analysis methods and solvents used for drug substances;
   D. Drug substances for investigational use (only if it is deemed necessary by the Minister of Ministry of Food and Drug Safety specifically for the quality inspection)
3. Deleted <Oct. 28, 2016>;
4. Deleted <Oct. 28, 2016>;
5. Deleted <Oct. 28, 2016>;
6. Deleted <Oct. 28, 2016>

(2) Notwithstanding paragraph (1), when registering drug substances manufactured using the same facility at a manufacturing site announced pursuant to Article 16 (1), data referred to in Subparagraph 1 of Paragraph (1) may not be submitted if determined so by the Minister of Ministry of Food and Drug Safety. <Newly established, Oct. 28, 2016>

(3) The Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS may perform quality examination or on-site inspection to judge whether DMF application pursuant to paragraph (1) conforms to the criteria as announced by the Minister of Ministry of Food and Drug Safety. <Revised on Aug. 21, 2014, Oct. 28, 2018>

(4) A person who intends to file a DMF pursuant to paragraph (1) shall pay a fee as announced by the Minister of Ministry of Food and Drug Safety (including overseas on-site inspection expenses if it is necessary to carry out). <Revised on Oct. 28, 2016>

(5) Details concerning preparation of documents pursuant to each subparagraph of paragraph (1), requirement of data and scope for exemptions, etc. shall be announced by the Minister of Ministry of Food and Drug Safety. <Revised on Oct. 28, 2016>

Article 16 (Drug Master File Registration Log & Certificate of Registration, etc.) If a DMF is submitted and the relevant active pharmaceutical ingredient is registered in accordance with Article 15 of this Regulation and Article 31-2 (2) of the Act, the Minister of Ministry of Food and Drug Safety shall enter the following information into the DMF registration log (including electronic DMF registration log) and issue the certificate of drug substance registration of Form (a certificate in electronic form is included. Hereinafter the same shall apply) of No. 17 to the applicant. In such case, the Minister of Ministry of Food and Drug Safety shall publicly announce the following information on the Internet or others. <Revised on Oct. 28, 2016>

1. Composition and names of the relevant drug substances;
2. Name of the DMF holder;
3. Registration number and date of registration;
4. Name and address of a manufacturing site;
5. If data under Article 15 (2) are not attached, specify that fact.

Article 17 (Application for Change of Drug Master File, etc.)

(1) A person who intends to change an important matter falling under any of the following subparagraphs of Drug Master File pursuant to the main part of Article 31-2 (3) of the Act shall submit a change application form of the Form No. 16 (including an electronic document) together with the certificate of Drug Master File, explanatory statement (including an electronic explanatory statement) and documents which can verify the reason for change to the Minister of Ministry of Food and Drug Safety.

1. Change of location of manufacturing site: Provided, That it shall not apply to case where the location is changed by administrative district reorganization;
2. Change of raw material pursuant to Annex 1 chapter I. 13 (including catalysts, organic solvents,

etc.), manufacturing process or batch scale among manufacturing methods of drug substances: Provided, That it shall apply to scale-up of 10 times or bigger only concerning the change of batch scale;

3. Change of material of immediate container or package of drug substances, storage method thereof or use-by date;
4. Change of analytical method of drug substances (it shall apply to cases where it is changed to a method which is not listed on the criteria of medicinal products, etc. pursuant to the Pharmacopoeia of Republic of Korea and Article 52 of the Act or official compendia pursuant to Article 4 (1) 1 B);
5. Any other cases which requires the register of change announced by the Minister of Ministry of Food and Drug Safety.

(2) A person who intends to change a matter any other than matters falling under each subparagraph of paragraph (1) concerning Drug Master File pursuant to the proviso of the main part of Article 31-2 (3) of the Act shall report the changed matter to the Minister of Ministry of Food and Drug Safety together with the certificate of Drug Master File(a case issued in electronic form is not included) pursuant to those prescribed by the Minister of Ministry of Food and Drug Safety until January 31 every year.

(3) When a change of Drug Master File is applied or reported pursuant to paragraph (1) or (2), the Minister of Ministry of Food and Drug Safety shall put changed matters on the registration log of Drug Master File and the certificate of Drug Master File pursuant to Article 16, and return the certificate of Drug Master File. In this case, the Minister of Ministry of Food and Drug Safety shall notify the changed matter through the Internet, etc. <Amended 2021. 3. 8.>.

(4) The Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS may perform quality examination or on-site inspection to judge whether the change of DMF application pursuant to paragraph (1) conforms to the criteria pursuant to Article 15 (2). <Revised on Aug. 21, 2014>

(5) A person who applies for change of Drug Master File pursuant to paragraph (1) shall pay a fee (including overseas on-site inspection expenses if it is necessary to carry out) as announced by the Minister of Ministry of Food and Drug Safety.

Article 18 Deleted <March 13, 2015>

Article 19 (Calculating Method, etc. of Expiration Date of Marketing and Notification) An expiration date under Article 31-5 Paragraphs 1 and 2 of the Act shall be calculated from the date of each of the following subparagraphs.

1. Items for which approval for manufacturing, sales and importation has been granted or notification has been filed on or after January 1, 2013: the date of approval or the date of notification

2. Items for which the re-review period for new drugs, etc. granted at the time of marketing approval and import expires on or after January 1, 2013: The day following the expiration date of the re-review period
3. Items for which marketing approval or product notification has been renewed: the day following the expiration date of the previous expiration date.

4. Items that do not fall under each subparagraph of Article 31-5 (1) of the Act after obtaining change approval or change notification: the date of change approval or change notification
5. Items for which obtained change approval as an item non-drugs for export after obtaining change approval(change notification shall be included. Hereinafter the same shall apply to this subparagraph): The date of approval or the date of notification of the product before obtaining change approval to drugs for export.

[newly established on July 21, 2022]

Article 20 (Renewal Application, etc. of marketing approval or registration of Manufacture, sales and importation)

(1) A person who intends to renew marketing approval or product report of manufacture, sale and importation of medicinal products pursuant to Article 31-5 (3) and Article 42 (5) of the Act shall submit an application form or a report form provided in the Form No. 20 (including an electronic format) together with documents or data of each of the following subparagraphs (including electronic documents) to the Minister of Ministry of Food and Drug Safety (it refers to the Commissioner of Regional FDS in case of renewal of approval for manufacturing and sale or import of products that require to demonstrate the equivalence of medicinal products or renewal of registration for products pursuant to Article 5 (2). It also applies to the below paragraphs (2) and (3)) until six months before the expiration date pursuant to Article 31-5 (1) and (2) of the Act. <Revised on Sep. 25, 2015, April 25, 2018>

1. Safety control data collected during expiry period and follow-up actions;
2. Use state and relevant actions concerning safety in foreign countries;
3. Quality control date collected during expiry period;
4. Matters concerning labelling;
5. Data concerning manufacturing and import performance;
6. Copy of certificate of marketing approval or certificate of completion of product report(each case issued in electronic form is not included)

(2) When the submitted data are deemed appropriate after being reviewed against approval or report criteria pursuant to Articles 2 to 5, 7, 8, 11, 12, 69 to 71, and 85, the Minister of Ministry of Food and Drug Safety shall issue a certificate of marketing approval provided in the Attached Form No. 10 or certificate of completion of notification provided in the Form No. 13.

(3) When marketing approval or product report of manufacture, sale and importation of medicinal products is not renewed pursuant to Article 31-5 (4) of the Act, the Minister of Ministry of Food and Drug Safety shall notify the result in writing with the specific reason to the person who submitted an

approval application form or a registration form.

(4) Details concerning preparation of documents pursuant to paragraph (1), requirement of data and scope for exemptions, etc. shall be announced by the Minister of Ministry of Food and Drug Safety.

(5) A person who intends to renew marketing approval or notification of manufacture, sale, or import of medicinal products pursuant to paragraph (1) shall pay a fee(On-site inspection in foreign countries expense is included) as announced by the Minister of Ministry of Food and Drug Safety. <Amended on Oct 14, 2020>.

Article 21 (Exception to Renewal of Marketing Approval of Manufacture, Sales and Importation)

"Medicinal products that have failed to be manufactured owing to extenuating circumstances prescribed by Ordinance of the Prime Minister" specified in the proviso of Article 31-5 (5) of the Act means medicinal products that have failed to be manufactured owing to lack of demand, instable supply of raw materials and other reasons, falling under any of the following subparagraphs.

1. Orphan drugs;
2. Medicinal products as prescribed in Article 13 (4) 7 of the Regulation on Medical Treatment Benefits of the National Health Insurance;
3. Biological medicinal products manufactured with the use of human or animal-derived fluids, etc.;
4. Medicinal products which are required to be stored and controlled by the country in order to prepare for national disaster situation; and
5. Other medicinal products corresponding to those falling under subparagraphs 1 to 4, as announced by the Minister of Ministry of Food and Drug Safety.

Article 22 (Re-examination of New Drugs, etc.)

(1) Re-examination period concerning products which shall be re-examined pursuant to Article 32 (1) or Article 42 (5) of the Act shall be as follows: <Revised on Sep. 25, 2015>

1. Products of which re-examination period is 6 years from the date of marketing approval:
   A. new drugs;
   B. Prescription drugs of which active pharmaceutical ingredients are different from those of approved medicinal products in kind or mixing ratio;
   C. Prescription drugs of which active pharmaceutical ingredients are the same with those of approved medicinal products but are different in route of administration.
2. Products of which re-examination period is 4 years from the date of marketing approval:
   A. Prescription drugs of which active pharmaceutical ingredients and route of administration is the same with approved medicinal products but apparently different efficacy is added;
   B. Any medicinal products which are recognized as necessary to be re-examined by the Minister of Ministry of Food and Drug Safety.

(2) The Minister of Ministry of Food and Drug Safety shall put the re-examination period on the certificate of marketing approval when marketing approval of medicinal products falling under paragraph (1) is granted.

(3) Notwithstanding the provision of paragraph (1), the Minister of Ministry of Food and Drug Safety may exempt the re-examination of medicinal products falling under any of the following subparagraphs: <Revised on May, 2014>

1. Insecticides and others which will not be directly applied to human body;
2. Orphan drugs;
3. Products which are recognized as unnecessary to be re-examined by the Minister of Ministry of Food and Drug Safety due to the lack of novelty;
4. Products which are recognized by the Minister of Ministry of Food and Drug Safety that their safety and efficacy are fully secured;
5. Product of which the number of target pursuant to paragraph (4) is so small that it is difficult to fulfill the requirement of re-examination.

(4) The Minister of Ministry of Food and Drug Safety may prescribe the details concerning the number of target, the requirement of re-examination data, preparation method of data in reference to the re-examination pursuant to Article 32 (2) of the Act.

Article 23 (Application for Re-examination of New Drugs, etc.)

(1) A person who intends to receive re-examination pursuant to Article 32 (1) or Article 42 (5) of the Act shall submit a re-examination application form provided in Form No. 21 (including an electronic format) together with the results of a periodic reporting pursuant to Article 8, item A of the Safety Control Standards after Marketing of Medicinal Products, etc. in Annex 4-3 and the data from a comprehensive analysis and evaluation of these to the Minister of Ministry of Food and Drug Safety. <Revised on Sep. 25, 2015, Oct. 28, 2016>

1. Deleted <Oct. 28, 2016>
2. Deleted <Oct. 28, 2016>
3. Deleted <Oct. 28, 2016>
4. Deleted <Oct. 28, 2016>

(2) Deleted <Oct. 28, 2016>

(3) The Minister of Ministry of Food and Drug Safety shall examine products applied for re-examination pursuant to paragraph (1) and issue a letter of re-examination result notice provided in Form No. 22. <Revised on Oct. 28, 2016>

(4) A person who intends to apply for re-examination of new drugs pursuant to paragraph (1) shall pay a fee as announced by the Minister of Ministry of Food and Drug Safety.

Article 24 (Permission of Plans for Clinical Trial, etc.)

(1) A person who intends to obtain the permission of plans for clinical trials pursuant to Article 34 (1) of the Act shall complete and submit the application form for clinical trials (including an electronic format) in Form No. 23 together with the following documents (including electronic documents) and

data (including electronic documents) to the Minister of Ministry of Food and Drug Safety. <Revised on Aug. 21, 2014, Oct. 28, 2016, March 30, 2018>

1. Development plan;
2. Investigator's brochure;
3. Documents or data which prove that the product was manufactured in compliance with Good Manufacturing Practice for Medicinal Products in Annex 1 and Good Manufacturing Practice for Investigational Products in Annex 4-2. In this case, if the investigational medicinal product falls into one of the following products, documents or data which prove that the product was manufactured in compliance with the relevant GMP shall be additionally submitted.
   A. Biological products, etc.: Good Manufacturing Practice for Biological Products, etc. in Annex 3;
   B. Radiopharmaceuticals: Good Manufacturing Practice for Radiopharmaceuticals of Annex 3-2;
   C. Medicinal high-pressure gases: Good Manufacturing Practice for Medicinal Gases in Annex 3-3.

3-2. In the case of blood pharmaceuticals according to the subparagraph 8 of the Article 2 of「Blood Management Law」, documents or data which prove the Blood product under Article 2, Subparagraph 8 of the Blood Management Act was manufactured in compliance with Good Manufacturing Practice for Blood products in Annex 3-4.

4. Data on the manufacture and quality related to investigational products;
5. Data on the non-clinical trial results;
6. Data on past experiences of a test product to be used for clinical trial (applicable only if they can be submitted);
7. Data on institutions (hereinafter referred to as "clinical trial institution" that perform clinical trials pursuant to Article 34 (2) 2 of the Act, clinical trial sample analysis institution according to the same Paragraph(hereinafter referred to as "clinical trial sample analysis institution"). Data on investigators, contracted agency, etc.;
8. Regulations on compensation for victims of clinical trials;
9. Informed consent form for subjects;
10. The protocol.

(2) Matters which to be included in the protocol pursuant to paragraph (1), subparagraph 10 shall be as follows: <Revised on Sep. 25, 2015, Oct. 28, 2016>

1. Title of Study, phase, protocol number and its history of enactment and revision, etc.;
2. Summary of protocol;
3. Introduction (background, theoretical basis, benefit and risk assessment, basis for dose selection, etc.);
4. Purpose of the study;

5. Study population (number of subjects, inclusion criteria, exclusion criteria and drop out criteria, etc.);
6. Contents of the study design (study period, experimental group and control group, assignment, blindness and flow chart, etc.);
7. Standards for termination and early discontinuation of studies;
8. Information and management of investigational products (labelling and packaging, route of administration, methods of administration, storage conditions, drug accountability, collection and disposal, etc.);
9. Test methods and dosage schedule, etc. (schedule of administration and treatment, concomitant medication, prohibited drugs, adherence to treatment, etc.);
10. Test procedures and evaluation (schedule of visits, test schedule, endpoints for efficacy and safety, reporting of adverse events, etc.);
11. Data analysis and statistical considerations (analysis set, statistical analysis method, standards of judgment, basis for timing of the analysis, and the number of subjects, etc.);
12. Data management (record, collection, access, protection, retention, etc.);
13. Ethical considerations and administrative procedures (regulations such as GCP, consent procedures, etc.; compliance with ethics; measures to protect subjects' safety, announcement of results, confidentiality of patient records; quality control and assurance of reliability, etc.);
14. Information on a person who intends to conduct clinical trials (hereinafter referred to as the "sponsor"), name and position of the principal investigator;
15. Trial method implemented for identifying equivalence of two preparations(limited to the case of conducting bioequivalence trial in clinical trials). However, for products that are determined to be equivalent to a reference drug as a result of a comparative dissolution test with the reference drug to be used for the bioequivalence study, the comparative dissolution test method may not need to be included if there is no change in composition, manufacturing methods and the manufacturer of the product after conducting a comparative dissolution test.
16. Other necessary matters for safe and scientific implementation of clinical trials.

(3) A person who intends to apply for approval for changes to the clinical trial plan approved pursuant to Article 34 (1) of the Act shall submit the application for approval for changes in the clinical trial plan in Form No. 23 (including an electronic application form) to the Minister of Ministry of Food and Drug Safety along with the clinical trials plan (including electronic documents), a letter stating the reasons for changes (including electronic documents), and documents or data (including electronic documents, and only if necessary) under subparagraphs 1 to 9 of Paragraph (1). <Newly established, Oct. 28, 2016>

(4) In the changes of clinical trial plan, changes in the protocol that fall under any of the following subparagraphs shall be subject to approval for changes pursuant to Paragraph (3). <Newly established, Oct. 28, 2016>

1. Changes in the study purpose;

2. Changes to the applicant;
3. A change that significantly affects the safety of subjects or the reliability of the study result, corresponding to any of the following items:
   A. As a change in the study population, significant changes in the number of subjects, changes in the inclusion and exclusion criteria of the subjects, or relaxation of the dropout criteria;
   B. As a change in the test design, addition or exclusion of experimental group or control group;
   C. <Deleted> <Oct 14, 2020>
   D. As a change in the information about investigational products, relaxation of the standards, deletion of test items, or changes of the manufacturer;
   E. <Deleted> <Oct 14, 2020>;
   F. As a change in the safety and efficacy, changes of endpoints or evaluation methods;
   G. Other changes prescribed by the Minister of Ministry of Food and Drug Safety

(5) Among changes in the clinical trial plan, changes falling under any of the following items shall be reported to the Minister of Ministry of Food and Drug Safety pursuant to proviso to Article 34 (1) of the Act: <Newly established, Oct. 28, 2016>

1. Clinical trial institution or clinical trial sample analysis institution;
2. Change of the principal investigator;
3. As a change falling under any of the items of Paragraph (4) 3, a change that does not significantly affect the safety of subjects or the reliability of study results;

3of 2. Addition of test or control group

3of 3. Changes in Criteria for Ending Clinical Trials and Early Discontinuation

3of 4. Change of administration method and administration period for clinical trial subjects

3of 5. Changes in safety and efficacy evaluation methods for investigational drugs

4. Other changes in the exploratory endpoints;
5. Deleted<Oct, 25, 2018>

(6) Notwithstanding Paragraphs (1) and (3), if approval is granted by the Minister of Ministry of Food and Drug Safety with regards to the standards of preparation of data necessary for approval for clinical trials or approval of changes pursuant to Article 35 (2) of the Act, submission of data or documents under Paragraph (1) 1 to 10 may be waived. <Newly established, Oct. 28, 2016>

(7) If a review of the application for approval of the clinical trials plan submitted pursuant to Paragraph (1) or the application for approval of changes in the clinical trials plan submitted pursuant to Paragraph (3) has determined that they are appropriate, the Minister of Ministry of Food and Drug Safety shall issue a letter of approval of the clinical trials plan in Form No. 24 by assigning an approval number for each plan. And when approving changes, he/she shall describe the matters that have changed in the section for changes and measures taken in the letter of approval. <Revised on Oct. 26, 2016>

(8) The studies falling under any of the following subparagraphs shall be excluded from the approval of the Minister of Ministry of Food and Drug Safety under Article 34 (1) of the Act pursuant to Article 34 (2) of the Act. <Revised on Oct. 28, 2016>

1. Observation of clinical effects on items approved for medicinal products, etc. available in the market and studies conducted to investigate adverse events;
2. Studies for the purpose of collecting data on safety and efficacy for approved efficacy and effectiveness etc. of medicinal products, etc. on sale;
3. Studies using medicinal products, etc. on sale to develop treatments for terminal cancer or acquired immunodeficiency which are life-threatening because there is no substitute drug or standard treatment method, etc., and thus it is difficult to expect a satisfactory effect with existing treatment method;
4. Studies using quasi-drugs;
5. When cases of using other medicinal products, etc. on sale, which is not directly related to safety or is not likely to cause ethical problems and prescribed by the Minister of Ministry of Food and Drug Safety.

(9) Details about the scope, requirements, instructions and timing of preparation of data to be submitted when applying for approval of clinical trial plan pursuant to Paragraphs (1) and (2) or when applying for approval of changes to the clinical trial plan or reporting changes pursuant to Paragraphs (3) to (5), the scope of data of which submission may be waived, and issuance of the letter of approval, etc. of the clinical trial plan shall be determined and notified by the Minister of Ministry of Food and Drug Safety. <Revised on Oct. 28, 2016>

(10) A person who desires to get permission for clinical trial plan or changes thereof pursuant to paragraphs (1) or (3) shall pay a fee as prescribed by the Minister of Ministry of Food and Drug Safety. <Revised on Oct. 28, 2016>

Article 25 <u>Deleted <Oct. 25, 2018></u>

Article 26 (Clinical trial at Medical Institutions Other Than Clinical Trial Institutions)

"Clinical trials as prescribed by the Ordinance of the Prime Minister" in accordance with the proviso of Article 34 (3) 1 of the Act shall mean one of the following clinical trials.

1. Clinical trials of medicinal products used for treatment of certain diseases widely occurred in a limited area of Si/Gun/Gu where there is no clinical trial institution, such as malaria;
2. Clinical trials of medicinal products mainly used for treatment or minor symptoms at specialized hospitals designated in accordance with Article 3-5 of the Medical Service Act, as accepted by the Minister of Ministry of Food and Drug Safety; and
3. Other clinical trials for which participation of medical institutions other than clinical trial institutions is deemed necessary when considering the nature of the clinical trial, as accepted by the

Minister of Ministry of Food and Drug Safety.

Article 27 (Collective Facilities)

"Collective facilities as prescribed by the Ordinance of the Prime Minister" in the body of Article 34-2 (3) Subparagraph 1 of the Act shall mean the following facilities. <Revised on Dec. 13, 2017>

1. Children welfare facilities in accordance with Article 52 (1) 1, 2, 3 and 5 of the Child Welfare Act;
2. Housing facilities for the disabled in accordance with Article 58 (1) subparagraph 1;
3. Mental health facilities in accordance with Article 3, subparagraph 4 of the Act on the Improvement of Mental Health and the Support for Welfare Services for Mental Patients for Mental Patients (for mental hospitals, limited to mental hospitals equipped with accommodation facilities);
4. Housing welfare facilities for the elderly in accordance with Article 32 (1) subparagraph 1, 2 and Article 34 (1) subparagraph 1, 2 of the Social Services Act;
5. Welfare facilities for families consisting of mother and child (basic living support and self-living support), families consisting of father and child (basic living support and self-living support), families consisting unmarried mother and child (basic living support) and temporary supports in accordance with Article 19 of the Single-Parent Family Support Act;
6. General support facilities and juveniles support facilities in accordance with Article 5 (1) of the Act on the Prevention of Sexual Traffic and Protection, Etc. of Victims Thereof;
7. Facilities for protection of victims of sexual violence in accordance with Article 12 of the Act on the Prevention of Sexual Violence and Protection, Etc. of Victims Thereof;
8. Facilities for protection of victims of domestic violence in accordance with Article 7 of the Act on the Prevention of Domestic Violence and Protection, Etc. of Victims;
9. Facilities for the relief and rehabilitation established by a person with permission of such relief and rehabilitation business in accordance with Article 67 of the Act on Probation, Etc. (limiting to those having accommodation facilities);
10. Correction facilities in accordance with 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 Inmates;
11. Reform schools and juveniles classification center in accordance with the Act on the Treatment of Protected Juveniles, Etc.; and
12. Facilities for protection of foreigners in accordance with Article 52 (2) of the Immigration Control Act.

Article 28 (Application, etc. for Permission for Use of Investigational Products for Treatment Purpose)

(1) The “emergency patient prescribed by the Ordinance of the Prime Minister” in Article 34 (4) 2 of the

Act shall refer to the following patients:

1. A patient whose life is seriously or urgently threatened;
2. A patient for whom there is no alternative treatment because it is difficult to expect a therapeutic effect if the treatment timing is missed.

(2) A person who intends to apply for use of a medicinal product manufactured or imported for investigation use (hereinafter referred to as “investigational products”) for other than -clinical trial purposes in order to treat patients who fall under any of the subparagraphs of Article 34 (4) of the Act (hereinafter referred to as "permission of use for treatment purpose") shall submit to the Minister of Ministry of Food and Drug Safety the application for permission for use of investigational products for purpose of treatment or research and etc., for treatment purpose of research and etc., in Form No. 28 (including electronic applications) along with documents or data pursuant to Paragraph (3) or (4) based on each size of the number of concerned patients pursuant to proviso other than each subparagraphs of Article 34 (4) of the Act.

(3) A medical specialist who intends to apply for permission of use for treatment of individual patients shall submit all of the following documents or data along with the application for approval of use for treatment purpose in Paragraph (2):

1. Documents that can prove that the applicant has expertise and experience in the concerned disease as a specialist;
2. Medical records of patient subject
3. Data on medical findings(supporting data such as related tests result are included), including the content that the patient subject falls under Article 34 (4) 1 or 2 of the Act and the clinical evaluation that the use of investigational drugs may benefit rather than risk to the patient ;
4. Patient's informed consent, including the following:
   A. Purpose of use of investigational products;
   B. Dangers or inconveniences expected of patients;
   C. The fact that the applicant, a specialist, will inform the patient or the patient's agent without delay when obtaining new information that may affect the use of the investigational products;
   D. The fact that the patient's decision to use the investigational products is voluntary;
   E. The fact that patients can refuse to use investigational products without loss of original benefits he/she could receive and that they can be discontinued at any time during use;
   F. The fact that the patient must pay the cost if provider of the investigational products charges the patient;
5. Providers' statement of intent to provide investigational products to be used.

(4) A person who intends to apply for permission of use for treatment purpose for two or more patients shall submit the application for permission for use of investigational products for treatment purpose along with the following documents or data:

1. Plan for use including each of the following items:

A. Purpose and reasons for use of investigational products;
B. Methods of collecting data related to safety and efficacy;
C. Patient inclusion criteria
D. Latest investigator's brochure or equivalent data on safety and efficacy;
E. Patient's informed consent form (when billing patients pursuant to Article 29, that fact shall be included.)
F. Among matters listed in each subparagraph of Article 24 (2), matters necessary for the use of pertinent investigational products.

2. Data in accordance with the following categories, which can prove a clinical effect for the disease that was aimed to be treated with the investigational products:
   A. For treating patients of a large scale pursuant to Article 34 (4) 1 or Article 28 (1) 1 of the Act (Refers to more than 25 people. The same shall apply hereafter.): Clinical trial results showing that the investigational medicinal product has a clinical effect for the concerned diseases in the early-phase clinical trial;
   B. For treating patients of a large scale pursuant to Subparagraph 2 of Paragraph (1): Clinical trial results for permission, notification, etc. as prescribed by Article 31(2), (3) or Article 42 (1) of the Act for domestic marketing of investigational medicinal product, or equivalent data;
   C. For treating patients of a small scale (refers to more than 2 and less than 25): Evidentiary data which can show that the investigational medicinal product has a clinical effect for the concerned disease and can reasonably explain the reasons why the period of administration and dosage are safe along with the pharmacological effect for the concerned disease.

(5) The Minister of Ministry of Food and Drug Safety shall review the application for use of investigational products for treatment purpose and the attached documents or data submitted pursuant to paragraphs (2) to (4), and if it is deemed appropriate, issue the letter of approval for use of investigational products for purpose of treatment or research and etc. in Form No. 29.

(6) If a person who has obtained the approval of use for treatment purpose pursuant to Paragraph (5) intends to change the details of approval, he/she shall obtain the approval for change from the Minister of Ministry of Food and Drug Safety by attaching documents or data that serve as the basis of change to the application for approval for changes to the use of investigational products for purpose of treatment or research and etc. in Form No. 30. In this case, the Minister of Ministry of Food and Drug Safety shall review the application for approval of changes and the attached documents or data and, if the validity is recognized, reissue the letter of approval for use of investigational products for purpose of treatment or research and etc. in Form No. 29.

(7) A person who has used an investigational product after obtaining the approval of use for treatment purpose pursuant to Paragraph (5) shall provide the supplier of the investigational product with

information that have been gathered after the use, such as adverse events observed in relevant patients, effectiveness, follow-up results on efficacy and safety, etc. without any delay after completion of its use. However, if any unexpected, serious adverse drug reactions occur, the person shall report it to the investigational product supplier pursuant to Subparagraphs 7 (K) of Annex 4. <Amended 2022. 12. 7.>

(8) A person who provided investigational drugs approved for use for therapeutic purposes in accordance with Paragraph 5 shall comply with the following items. <Newly established Dec 7 2022>.

1. Prepare provision standards in consideration of the clinical trial stage of the relevant investigational product, and store and manage provision details and safety information submitted
2 . Within 20 days from the date of receipt of the information collected pursuant to Paragraph 7, the results of the use of investigational drugs shall be prepared and reported to the Minister of Ministry of Food and Drug Safety, however, if unexpected serious adverse drug reactions occurs, it shall be reported to the Minister of Ministry of Food and Drug Safety in accordance with Appendix 4 Subparagraph 8 Item D.

(9) Notwithstanding Paragraph 8 Subparagraph 2, in cases where it is difficult to report because the person who provided the investigational product lives overseas, etc., in cases determined by the Minister of Ministry of Food and Drug Safety, those who have obtained approval for use for treatment purposes in accordance with Paragraph 5 for individual patients Investigational drug use results and serious adverse drug reactions can be reported to the Minister of Ministry of Food and Drug Safety. <Newly established 12 7, 2022>.

(10) A person who obtained approval of use of Investigational Drug for purpose of treatment to treat two or more patients in accordance with the Article 5 may provide the Investigational Drug with the Clinical Trial Institution.

(11) A person who intends to use the investigational drug provided with the Clinical Trial Institution in accordance with Article 10 shall receive an approval from the Instititutional Review Board(Hereinafter refers to 'Review Board') of the Institution in accordance with Annex 4 of the Article 6.

(12) In addition to the matters prescribed by the paragraphs (1) to (11), detailed methods and procedures required for the approval of use of investigational products for treatment purpose shall be prescribed and notified by the Minister of Ministry of Food and Drug Safety.

[Revised on of the Entire Article, Dec. 13, 2017]

Article 29 (Billing for Approval for Use of Investigational Products for Treatment Purpose, etc.)

(1) The provider of an investigational product may charge the patient to whom the investigational product is administered the cost of the corresponding investigational product at its cost of production (refers to the costs directly incurred in the manufacture of investigational product used on individual patients excluding expenses for facilities and environmental management, etc. and research and development costs).

(2) If the provider of an investigational product intends to charge the expense pursuant to Paragraph (1), he/she may send the following documents to the person applying for approval of use for treatment

purpose under Article 28 (2) or the person applying for approval of the change under Paragraph (6) of the same Article. And the person applying for approval of use for treatment purpose or approval for change shall submit it to the Minister of Ministry of Food and Drug Safety:

1. The cost accounting report prepared by the registered CPA or accounting corporation within one month of the application date pursuant to the Certified Public Accountant Act;
2. A bill issued to the patient;
3. Documents that can provide evidence of no intention to market investigational products domestically without obtaining approval or making a report pursuant to Article 31(2), (3) or Article 42 (1) of the Act (when intending to use for large-scale patients, the status of enrollment of subjects, the progress of the development and the development plan for the following year must be included to prove that completion of clinical trial for marketing authorization is possible.)

(3) If granting the approval for use for treatment purpose which is charged to the patient pursuant to Paragraph (1), the Minister of Ministry of Food and Drug Safety shall issue the letter of approval for use of investigational products for purpose of treatment or research and etc. for treatment purpose of research and etc. in Form No. 29 and provide a relevant billing period within a period of one year.

(4) A person who intends to extend the period granted under Paragraph (3) or re-extend the period extended under Paragraph (5) shall submit the application for extension of period of billing for investigational products in Form No. 31 (including an electronic application form) to the Minister of Ministry of Food and Drug Safety along with the documents specified in each subparagraph of Paragraph (2).

(5) If the application for extension of period of billing for investigational products submitted pursuant to Paragraph (4) is deemed to be valid based on a review, the Minister of Ministry of Food and Drug Safety may extend or re-extend the period granted under paragraph (3) or (5) within a period of one year.

[Revised on of the Entire Article, Dec. 13, 2017]

Article 29-2(Application etc. for use of research on Investigational Products or analysis)

(1) Those who receive approval for plan of clinical trial(except for bioequivalence study. It is identical in the Article below) according to the Paragraph 1 of the Article 34 apply for approval(hereinafter referred to as "Approval of use for the purpose of research and etc.") of use for the purpose of research analysis in accordance with the subparagraph of the paragraph of the Article 34 shall submit the application(including the application in the electronic document) for use approval for the treatment purpose · research of clinical trial pharmaceuticals of the attached paper no. 28 to the Minister of Food and Drug Safety by attaching the use plan(including electronic document) which includes the details of each Subparagraph below.

1. Specific use purpose of Investigational Products.
2. Product name and amount, user and use location of Investigational Products.

3. Collection and disposal plan after the completion of use of Investigational Products and etc.

(2) The Minister of Food and Drug Safety shall issue use approval for purpose of treatment or research and etc. of Investigational Products in Form No. 29 in the case in which the validity is recognized after the review of the application of application of approval for uses such as researches on Investigational Products submitted in accordance with the Paragraph 1.

(3) In the case in which those who received the approval for uses such as researches in accordance with the Paragraph 2, they shall submit the application for approval for changes of purposes such as therapy purpose · reseach and etc. of pharmaceuticals for clinical trial in form No. 30 written form of the Attached paper(including the application of electronic document) to the Minister of Food and Drug Safety by attaching document or data proving changes.

(4) The Minister of Food and Drug Safety shall reissue the approval for uses such as therapy purpose · research and etc. of pharmaceuticals for clinical trial in the no. 29 writing form of the Attached paper in the case in which the validity is recognized after reviewing the application for approval for changes submitted in accordance with the Paragraph 3.

[Newly established in this Article Oct. 25, 2018]

Article 30 (Standards, etc. of Conducting Clinical Trials)

(1) Clinical trials pursuant to Article 34 of the Act shall be conducted pursuant to criteria of the following each subparagraph and Annex 4 Good Clinical Practice. <Revised on Aug. 21, 2014, Oct. 28, 2016, Dec. 13, 2017, Oct.25. 2018, June.12, 2019>

1. The sponsor, clinical trial institution or the head of clinical trial sample analysis institution shall conduct clinical trial in a safe and scientific way in accordance with protocol or protocol amendment for clinical trial which is approved by the Minister of Ministry of Food and Drug Administration.
2. A medical institution which is not a clinical trial institution pursuant to the proviso to Article 34 (3) subparagraph 1 of the Act shall conduct clinical trials under the management and supervision of a clinical trial institution.
3. The sponsor shall select the investigator responsible for the conduct of the clinical trial among people who have expertise, a sense of ethics and full experience to conduct the clinical trial of the medicinal product, etc.
4. The investigator shall obtain a written consent from a trial subject or subject's representative (only where the consent cannot be received from a trial subject) according to the Article 34-2 (3) Subparagraph 2 · 3 of the law and Annex 4 Good Clinical Practice.
5. The sponsor, clinical trial institution or the head of clinical trial sample analysis institution shall take safety measures for the trial subject.

6. The sponsor shall start a clinical trial within two years from the date of approval.

7. The sponsor shall provide investigator's brochure pursuant to Annex 4(2) item A with investigators before a clinical trial pursuant to what the Minister of Ministry of Food and Drug Safety prescribes according to the same subparagraph item B.

8. In cases where new data or information concerning safety or efficacy is obtained, the sponsor shall inform it to investigators without delay.

9. The sponsor shall use investigational products manufactured in accordance with requirements prescribed in Annex 1, Annex 3 (only biological products, etc. are applicable), Annex 3-2 (only radiopharmaceuticals are applicable), Annex 3-3 (only medicinal high-pressure gases are applicable), Annex 3-4 (only the case of the blood pharmaceuticals according to the subparagraph 8 of the Article 2 of「Blood Management Law」is applicable) and Annex 4-2.

10. A person who has already received approval for clinical trial plan shall submit such information to the Minister of Ministry of Food and Drug Safety according to the classification of each item below within the period if she/he conducts the said clinical trial.

A. Status of the first and final subjects of trial: within 30 days from the date of enrolling the first and last subjects of trial (in case of multi-national clinical trial, the date when the participation by the final subject is confirmed)

B. Status of observation completion for the last subject of the trial: within 20 days from the date of observation completion.

C. Progress status of clinical trial: the annual clinical trial status , until the end of March of the next year.

D. Final results of clinical trial: within 1 year from the date of observation completion of the last subject of trial(included the foreign subjects of trial in the case of multi-national clinical trial)

10-2. In regard to the implementation status of clinical trials each year, the head of the clinical trial institution shall attach the list of implementation status of clinical trials to the implementation status report of clinical trials (including an electronic report) in Form 32-2 and submit to the Minister of Ministry of Food and Drug Safety by the end of March of the following year

11. Deleted <Oct. 25, 2018>

12. The sponsor, the clinical trial institution, and the clinical trial sample analysis institution shall retain various data related to the clinical trial, including records of the clinical trial plan and the manufacture and management of the investigational drugs according to the classification of each of the following.

A. Data concerning clinical trials for marketing approval (including change approval) of the relevant investigational medicinal product: 3 years from the date of marketing approval; and

B.Data concerning clinical trials except A: 3 years from the date of the completion of clinical trial.

13. If any unexpected, serious adverse drug reactions occur, the person who has obtained the approval for clinical trial plan shall report it to the Minister of Ministry of Food and Drug Safety pursuant to Subparagraph 8 R of the Good Clinical Practices in Annex 4.

13-2. The head of clinical trial sample analysis institution shall comply with the criteria for proper implementation of clinical trial sample analysis such as plan establishment, implementation, quality management, data storage and others, as notified by the Minister of Ministry of Food and Drug Safety.

14. Before conducting a clinical trial in healthy subjects, the head of the clinical trial institution shall check whether or not they have participated in other clinical trials through internet homepages, etc. operated by the Minister of Ministry of Food and Drug Safety within 6 months by obtaining the consent of those who intend to participate in the clinical trial and exclude those who have participated in other clinical trials within 6 months.

(2) Details concerning the designation of a clinical trial institution pursuant to paragraph (1) shall be announced by the Minister of Ministry of Food and Drug Safety.

(3) The Minister of Food and Drug Safety can post the protocol which received approval or amendment approval change approval in accordance with the Article 34 of the law, and the data submitted according to each item of subparagraph 10 of paragraph 1 according to related laws in the homepage on the Internet which is operated by the Minister of Food and Drug Safety.

<Newly established Oct. 25, 2018>

Article 31 Deleted <Oct. 25, 2018>

Article 32 Deleted <Sep. 25, 2015>

Article 33 (Prohibition of Use of Investigational Products)

For the following clinical trials, etc., the Minister of Ministry of Food and Drug Safety may order actions, such as prohibition of use, recall and scrapping of investigational products used in clinical trials, etc., in accordance with Article 34 (6) of the Act: Provided, That if, even though a clinical trial falls under subparagraph 5 or 6, adverse effect on safety, rights, or welfare of subjects, or validity of the clinical trial is not expected or such violation is not repeated or intentional, the Minister of Ministry of Food and Drug Safety may call attention or order corrective actions.<Revised on Sep.25,2015. Dec.13,2017. Oct.25,2018>

1. If subjects participating in clinical trials and others may be exposed to unexpected serious disease or injury;
2. If medicinal products used in clinical trials and others are provided for commercial purpose, not for

the purpose of being used in clinical trials and others;

3. If the investigator's brochure is prepared to contain false information and provided as such;
4. If it is judged that investigational products do not have efficacy;
5. If matters or their changes approved in accordance with Article 34 (1) of the Act are violated; and
6. If the Good Clinical Practice regulations as prescribed in Annex 4 are violated.

Article 34 (Requirements for Designation of Clinical trial Institution and Procedures, etc.)

(1) The requirements for designation of clinical trial institution under Article 34-2 (1) of the Act are as follows: <Revised on Sep. 25, 2015>

1. Medial institutions falling into one of the following items;
   A. General hospitals under Article 3-3 of the Medical Service Act;
   B. Medical specialists training hospitals, training dental hospitals and training oriental medicinal hospitals under the Regulation on Training and Certification of Medical Specialists, the Regulation on Training and Certification of Dental Specialists, and the Regulation on Training and Certification of Oriental Medical Specialists;
   C. Specialized hospitals designated in accordance with Article 3-5 of the Medical Service Act;
   D. Hospitals equipped with personnel and facilities satisfying the requirements for designation of training hospitals and training dental hospitals in accordance with Article 7 of the Regulation on Training and Certification of Medical Specialists and Article 7 of the Regulation on Training and Certification of Dental Specialists;
   E. Clinical trial center located in the high-tech medical complex designated in accordance with Article 6 of the Special Act on the Designation and Support of High-Tech Medical Complexes.
2. The clinical trial institution shall satisfy the requirements for facilities, specialized personnel, equipment and others necessary for the conduct of clinical trials, as notified by the Minister of Ministry of Food and Drug Safety.

(2) A person who intends to be designated as clinical trial institution shall submit to the Minister of Ministry of Food and Drug Safety the application for designation of clinical study institution of Form No. 35 (including electronic application), together with the following documents (including electronic documents).

1. Deleted <Dec. 13, 2017>
2. Document proving that it falls into one of medical institutions as prescribed in the paragraph (1), subparagraph 1;
3. Documents relating to personnel, facilities, equipment and apparatus;
4. Standard operating procedures necessary for clinical trials;
5. Regulations on operation of institutional review board as prescribed in Annex No. 4 "Good Clinical Practice Regulations" and document relating to its organization. If it is intended to use the institutional review board designated by the Minister of Ministry of Food and Drug Safety

("designated IRB"), the contract shall be included. However, in the case of entrusting the review pursuant to the proviso of Article 34-2 (3) 5 of the Act, the consignment contract shall be attached.

(3) On receipt of the application under paragraph (2), the Minister of Ministry of Food and Drug Safety shall verify the following documents through the procedure for common use of administrative information pursuant to Article 36 (1) of the Electronic Government Act. However, for Subparagraph 2, if the applicant does not consent to the verification, he/she shall be instructed to submit the copy him/herself. <Revised on Dec. 13, 2017>

1. Certificate of corporation registration (limited to corporations);
2. Permit to open a medical institution pursuant to Article 27 (3) of the Enforcement Regulation of the Medical Service Act.

(4) On receipt of the application under paragraph (2), the Minister of Ministry of Food and Drug Safety may conduct investigation to verify if the applicant satisfies the requirements for designation.

(5) When designating a clinical trial institution, the Minister of Ministry of Food and Drug Safety shall issue the certificate of designation of clinical trial institution for medicinal products of Form No. 36.

(6) If a clinical trial institution intends to amend the designated information, it shall submit to the Minister of Ministry of Food and Drug Safety, the application for amendment to the designation of clinical trial institution for medicinal products of Form No. 35, together with the certificate of designation of clinical trial institution for medicinal products and other documents proving changes, within 30 days from the date of change.

(7) When approving the amendment, the Minister of Ministry of Food and Drug Safety shall describe changes in the certificate of designation of clinical trial institution for medicinal products.

(8) When designating a clinical trial institution or approving the amendment of the designation under paragraph (5) or (7), the Minister of Ministry of Food and Drug Safety shall disclose the information on name, address and representative of clinical trial institution on the Internet website.

(9) Matters to be reported to the Minister of Ministry of Food and Drug Safety by the clinical trial institutions pursuant to proviso to Article 34-2 (2) of the Act shall be as follows: <Newly established, Sep. 25, 2015>

1. Change of the head of the clinical trial institution;
2. Change of the location of the clinical trial institution according to administrative district reorganization.

(10) A person who intends to apply for designation of clinical trial institution or its amendment in accordance with paragraph (2) or (6) shall pay the fee as notified by the Minister of Ministry of Food and Drug Safety. <Revised on Sep. 25, 2015>

(11) In accordance with the proviso of Article 34-2 Paragraph 3 Subparagraph of the Act, the head of the clinical trial institution may consign review, etc including implementation of clinical trial to Central Clinical Trial Review Board (hereinafter referred to as “central review). <Newly established on July 21, 2022>

1. When the head of a clinical trial institution deems that an evaluation on the conduct of a clinical trial is urgently needed to respond to a public health emergency under the 「Special Act on the Promotion of Development and Emergency Supply of Medical Products in Response to Public Health Emergency」

2. When the head of each clinical trial institution deems that a unified review is necessary for a clinical trial to be conducted by multiple clinical trial institutions

3. Other cases determined by the Minister of Ministry of Food and Drug Safety, such as when the development of a new treatment is necessary because it is difficult to expect the effect of the existing treatment.

(12) If the head of the clinical trial institution recognizes that a professional review by another review committee is necessary pursuant to the proviso of Article 34-2 (3) 5 of the Act, he/she may consign review, etc including implementation of clinical trial to other review committees <Newly established on July 21, 2022>

(13) Details required for the designation, operation, and management of clinical trial institutions shall be determined and notified by the Minister of Ministry of Food and Drug Safety. <Amended on Sep 25, 2015, July 21, 2022>

Article 35 (Requirements for Designation of Clinical trial sample analysis institution, etc.)

(1) The requirements for designation as clinical trial sample analysis institution according to the Subparagraph 2 of the Paragraph 1 of the Article 34-2 shall be as follows: < **Deleted** >

1. Persons determined and notified by the Minister of Food and Drug Safety shall be appointed as experts required for analysis such as persons responsible for analysis and data storage

2. Equipment and facilities determined and notified by the Minister of Food and Drug Safety for storage · handling · process · analysis of samples such as freezer and data storage room shall be prepared.

3. For quality management of sample analysis such as matters regarding writing of standard operation procedures for analysis work and etc., the criteria determined by the Minister of Food and Drug Safety shall be applied.

(2) Those who hope to be designated as clinical trial sample analysis institution shall submit the application for designation of clinical trial sample analysis institution (including electronic document) of the no. 37 of the Attachment to the Minister of Food and Drug Safety by attaching documents(including electronic documents) of each subparagraph below.

1. Documents regarding status of personnel(including documents proving qualification and career of specialized personnel)

2. Documents regarding status of equipment tool and facilities (including floor plan in the case of facilities)

3. Data determined and notified by the Minister of Food and Drug Safety for proving the ability of clinical trial sample analysis [limited only to the case of hoping to be designated for analysis of pharmacokinetics

between two products

4. Standard work instruction required for conducting clinical trial sample analysis

< Deleted >

(3) On receipt of the application under paragraph (2), the Minister of Ministry of Food and Drug Safety shall verify certificated of corporation registration(only corporations are applicable) shall be confirmed through the procedure for common use of administrative information pursuant to the Paragraph 1 of the Article 36 of the Electronic Government Act.

(4) On receipt of the application under paragraph (2), the Minister of Ministry of Food and Drug Safety may conduct investigation to verify if the applicant satisfies the requirements for designation.

(5) When designating a clinical trial sample analysis institution after verifying application according to the Paragraph 2, certificated of designation of clinical trial sample analysis institution of the no. 38 writing form of the Attachment shall be issued to applicant.(designation in electronic form is included. Hereinafter the same shall apply) <Amended 2021. 3. 8.>.

(6) Those who intend to amend the designation as clinical trial sample analysis institution, it shall submit to the Minister of Ministry of Food and Drug Safety, the application of amend designation of clinical trial sample analysis institution (excluding application in electronic document) to clinical trial sample analysis institution of Form No. 37, together with the certificate of designation of bioequivalence study institution and other documents proving changes, within 30 days from the date of change.

(7) In the case of changed designating clinical trial sample analysis institution after examining application according to the paragraph 6, Certificate of designation the designation document of clinical trial sample analysis institution including changed matters shall be issued to applicant.

(8) When issuing or providing certificate of designation of clinical trial sample analysis institution in accordance with paragraph (5) or (7), clinical trial sample analysis institution, the Minister of Ministry of Food and Drug Safety shall disclose the information on name, address and representative of bioequivalence study institution on the Internet website.

(9) A person who intends to apply for designation of clinical trial sample analysis institution in accordance with the paragraph (2) or (6) shall pay the fee as notified by the Minister of Ministry of Food and Drug Safety. <Revised on Sep. 25, 2015>

(10) Except as otherwise expressly provided for in paragraph 1 to the paragraph 9, detailed procedures for designation, operation of clinical trial sample analysis institution shall be notified by the Minister of Ministry of Food and Drug Safety. [Revision of whole text Oct. 25, 2018]

Article 36 (Responsibilities of clinical trial sample analysis institution)

"Matters as prescribed by the Ordinance of the Prime Minister" in the subparagraph 5 of the Paragraph 3 of the Article 34-2 (3) shall mean requirements for clinical trials and bioequivalence studies in accordance with Articles 30 and 31. <Revision Oct. 25, 2018, and Jun. 12, 2019> [Revision of title Oct. 25, 2018]

Article 37 (Designation of Non-Clinical Trial Institution)

(1) A person who intends to be designated as non-clinical trial institution under Article 34-3 (2) of the Act ("non-clinical trial institution") shall meet requirements for facilities, specialized personnel, equipment and others for the fields of the non-clinical trial institutions (meaning toxicological study, mutagenicity study, analytical tests and others), as notified by the Minister of Ministry of Food and Drug Safety. <Revised on Sep. 25, 2015>

(2) A person who intends to be designated as non-clinical trial institution shall submit to the Minister of Ministry of Food and Drug Safety the application for designation of non-clinical study institution of Form No. 39 (including electronic application), together with the following documents (including electronic documents).

1. Documents relating to personnel (including documents demonstrating qualifications and experiences);
2. Documents relating to facilities, equipment and apparatus;
3. Documents or information demonstrating the conduct of non-clinical trials in accordance with notifications by the Minister of Ministry of Food and Drug Safety, to prove the capability for non-clinical trials;

(3) On receipt of the application under paragraph (2), the Minister of Ministry of Food and Drug Safety shall verify the certificate of corporation registration (limiting to corporations) through the procedure for common use of administrative information in accordance with Article 36 (1) of the Electronic Government Act.

(4) On receipt of the application under paragraph (2), the Minister of Ministry of Food and Drug Safety may conduct investigation to verify if the applicant satisfies the requirements for designation.

(5) When designating a non-clinical trial institution, the Minister of Ministry of Food and Drug Safety shall issue the certificate of designation of non-clinical trial institution of Form No. 40(designation in electronic form is included. Hereinafter the same shall apply) .

(6) If a non-clinical trial institution intends to amend the designated information, it shall submit to the Minister of Ministry of Food and Drug Safety, the application for amendment to the designation of non-clinical trial institution of Form No. 39, together with the certificate of designation of non-clinical trial institution and other documents(excluding application in electronic document) proving changes, within 30 days from the date of change.

(7) When approving the amendment, the Minister of Ministry of Food and Drug Safety shall describe changes in the certificate of designation of non-clinical trial institution.

(8) When designating a non-clinical trial institution or approving the amendment of the designation under paragraph (5) or (7), the Minister of Ministry of Food and Drug Safety shall disclose the information on name, address and representative of non-clinical trial institution on the Internet website.

(9) A person who intends to apply for designation of non-clinical trial institution or its amendment in accordance with paragraph (3) or (6) shall pay the fee as notified by the Minister of Ministry of Food

and Drug Safety.

(10) Detailed procedures for designation, operation and control of bioequivalence study institutions shall be notified by the Minister of Ministry of Food and Drug Safety.

Article 38 (Responsibilities of Non-Clinical Trial Institution)

(1) "Matters as prescribed by the Ordinance of the Prime Minister" in Article 34-3 (3) of the Act are as follows: <Revised on Oct. 28, 2016>

1. The non-clinical trial institution shall prepare the non-clinical trial plan and conduct non-clinical trial according to the plan.
2. Inspection and audit to verify the reliability of the non-clinical trial shall be conducted by a person who does not have any interests in the relevant non-clinical trial.
3. The non-clinical trial institution shall be able to demonstrate that non-clinical trials were conducted in compliance with Good Laboratory Practice Regulations as notified by the Minister of Ministry of Food and Drug Safety.
4. The non-clinical trial institution shall maintain all documents and records relating to non-clinical trials for 3 years from the date of the relevant medicinal product manufacture, marketing, and. import approval.
5. Each year, the head of the non-clinical trial institution shall submit a report on the status of non-clinical trials in Form No. 34-2 (including reports in an electronic form) to the Minister of Ministry of Food and Drug Safety by the end of March of the following year.

(2) Detailed requirements for responsibilities of non-clinical trial institution under the paragraph (1) shall be notified by the Minister of Ministry of Food and Drug Safety.

Article 38-2 (Contents, Time, Method, etc. of Education such as Clinical Trial)

(1) The content of the training for clinical trials, etc. for workers related to clinical trials, etc. pursuant to Article 34-4 (1) of the Act shall be as follows:

1. Matters concerning professional knowledge necessary to improve the expertise of workers of clinical trials, etc.;
2. Matters concerning ethical literacy necessary for the protection, etc. of subjects of clinical trials, etc.;
3. Other matters necessary for workers of clinical trials, etc. to perform the study, etc.

(2) The "persons prescribed by the Ordinance of the Prime Minister" referred to in Article 34-4 (1) 4 of the Act shall means persons in the following subparagraphs:

1. Member of the institutional review board (IRB);
2. Persons performing quality assurance work in clinical trials at clinical trial institution;
3. < Deleted >

(3) The time for training on clinical trials, etc. to be given to the workers of clinical trials, etc. pursuant to

Article 34-4 (1) of the Act shall be announced by the Minister of Ministry of Food and Drug Safety within 40 hours each year taking into account the work experience and type of work, etc. In this case, during the training session for clinical trials, etc., the time of the training for clinical trials, etc. on the people who do not have a work experience in the relevant field such as the clinical trials, etc. and should receive before starting the work shall be notified by the Minister of Food and Drug taking into account the type of work, etc.

(4) Educational institutions for clinical trials under Article 34-4 (3) of the Act (hereinafter referred to as "educational institutions for clinical trials, etc.") may receive tuition fees from trainees, taking into account training materials, on-site practical exercise and lecturers. In this case, the tuition fee shall be determined by the head of the educational institutions for clinical trials, etc. on the basis of actual expenses.

(5) In addition to the matters prescribed in Paragraphs (1) to (4), detailed requirements about the contents, time, methods, procedures, etc. of the training for clinical trials, etc. shall be prescribed and notified by the Minister of Ministry of Food and Drug Safety.

[This Article is newly established. Sep. 25, 2015]

[Revision of title Oct. 25, 2018]

Article 38-3 (Designation of Educational Institutions for Clinical Trials, etc.)

(1) In order to be designated as an educational institution for clinical trials, etc., all of the following requirements shall be satisfied:

1. It shall correspond to one of the following items:
   A. A college or a junior college pursuant to Article 2 (1) or (4) of the Higher Education Act which has a department or major related to clinical trials, etc. such as medicine, pharmacy, nursing, etc.;
   B. An institution which conducts clinical trials, etc. and operates a program for enhancing the quality and ethics of clinical trials notified by the Minister of Ministry of Food and Drug Safety;
   C. A person who intends to conduct clinical trials pursuant to the Article 34 (1) of the Act (limited to cases where training for clinical trials, etc. are conducted only for affiliated employees);
   D. Other organizations or institutions performing related tasks such as clinical trials, etc.
2. It shall meet the requirements prescribed and notified by the Minister of Ministry of Food and Drug Safety for each item of Subparagraph 1, such as the organization, personnel, facilities, programs, experience, etc. necessary for education on clinical trials, etc.

(2) A person who intends to be designated as an educational institution for clinical trials, etc. shall attach the following documents (including electronic documents) to the application for designation as an educational institution for clinical trials (including an electronic application form) and submit to the Minister of Ministry of Food and Drug Safety:

1. Documents proving that you are a person who falls under any of the items in subparagraph 1 of

Paragraph (1);

2. Data on the operating organization, status of personnel to conduct training;
3. Data on the status of educational facilities and equipment;
4. In-house regulations on conducting training;
5. Data on curriculum, evaluation methods, and plans for implementation for each trainee;
6. Basis for calculation of the tuition fee.

(3) On receipt of the application pursuant to Paragraph (2), the Minister of Ministry of Food and Drug Safety shall verify the certificate of corporation registration (limiting to corporations) through the procedure for common use of administrative information in accordance with Article 36 (1) of the Electronic Government Act. And he/she may conduct an inspection of the actual status to assess whether the application meets the specified requirements. <Revised on Dec. 13, 2017>

(4) When designating an educational institution for clinical trials, etc., the Minister of Ministry of Food and Drug Safety shall issue a letter of designation of the educational institution for clinical trials in Form No. 40-3 to the applicant.

(5) If the educational institution for clinical trials intends to change the matters corresponding to any of each subparagraph below, he/she shall submit an application for change of designation of the educational institution for clinical trials in Form No. 40-2 of the attached paper (including an electronic application form) to the Minister of Ministry of Food and Drug Safety along with the designation of clinical education implementation institution documents to confirm changed matters within 30 days from the day on which the reasons for change occurred. However, in the case of changing matters besides each Item below, within 30 days from the date when change matters occur, the changed matters shall be reported to the Minister of the Food and Drug Safety and the designation of educational institutions for clinical trials shall be submitted.

1. Location (except for change from administrative district reorganization)
2. Educational course

(6) When making changes to the designation of educational institutions for clinical trial, the Minister of Ministry of Food and Drug Safety shall record and submit the matters that have changed in the form for designation of an educational institution for clinical trials.

(7) A person who intends to apply for the designation or change of designation of an educational institution for clinical trials pursuant to Paragraph (2) or (5) shall pay a fee determined and notified by the Minister of Ministry of Food and Drug Safety.

(8) The matters to be observed by the institution conducting training for clinical trials, etc. pursuant to Article 34-4 (4) of the Act shall be as follows:

1. Establish a plan to conduct education including the contents, etc. of education for the following year and submit it to the Minister of Ministry of Food and Drug Safety by Dec. 10 every year.
2. Issue a certificate to the person who has completed the training, record the details of the training such as the list of the persons who have completed the training, and keep it for 2 years from that

date.

3. Report the previous year's record on implementation of trainings to the Minister of Ministry of Food and Drug Safety by the end of February every year

(9) The Minister of Ministry of Food and Drug Safety may revoke the designation if the institution conducting training for clinical trials, etc. falls under any of the following subparagraphs. However, if it falls under Subparagraph 1, 2 or 5, the designation shall be canceled.

1. If the designation is given through false or illegal methods;
2. If a certificate is issued to a person who has not completed the education;
3. Failure to apply for change of designation in violation of Paragraph (5);
4. Failure to comply with the requirements of Paragraph (8);
5. Failure to provide education in accordance with the plan to conduct training pursuant to Paragraph (8) 1 of the Act without proper cause or to operate the training program for more than one year.

(10) In addition to the matters prescribed in the paragraphs (1) to (9), the details of the designation, operation, and compliance of the institutions conducting training for clinical trials, etc. shall be prescribed and announced by the Minister of Ministry of Food and Drug Safety

[This Article is newly established. Sep. 25, 2015]

[Revision of title Oct. 25, 2018]

Article 38-4 Article 38-4 (Designation and Operation of Clinical Trial Safety Support Institutions) ① A clinical trial safety support institution pursuant to Article 34-5 Paragraph 1 of the Act shall meet the following requirements.

1. A task force capable of carrying out and managing the affairs of each subparagraph of Article 34-5 (1) of the Act shall be established.

2. Professional personnel with sufficient knowledge and experience in clinical trials shall be deployed

3. A cooperative system shall be established with the review committee established and operated by the clinical trial institution.

② The Minister of Ministry of Food and Drug Safety may designate an institution or organization related to clinical trials that is recognized as suitable for the standards under Paragraph 1 as a clinical trial safety support institution.

③ "Other duties prescribed by the Ordinance of the Prime Minister" in Article 34-5 Paragraph 1 Subparagraph 6 of the Act refers to the following duties.

1. Management and operation of the computer system for clinical trial review

2. Establishment of a domestic and international cooperation system for safety management of clinical trials

3. Establishment and operation of a support center for clinical trial subjects to conduct counseling and

information provision pursuant to Article 34-5 (1) 4 of the Act

4. Development, dissemination, and management of programs to enhance the quality and ethics of clinical trials under Article 38-3 (1) 1 (b);

④ Matters necessary for the designation and operation of clinical trial safety support institutions other than those specified in paragraphs 1 through 3 shall be determined and notified by the Minister of Ministry of Food and Drug Safety.

[newly established on July 21, 2022]

Article 38-5 (Composition and Operation of the Central Review Board) ① A member of the Central Review Board is appointed by the head of clinical trial institutions based on the recommendation by the head of trial-related academic society or organization among those who have the experience and qualifications to review and evaluate the ethical, scientific, and medical aspects of clinical trials considering the gender. <Amended on Dec 7, 2022>

② The term of the member shall be two years.

③ The chairperson of the Central Review Board is elected among members

④ The chairperson of the Central Review Board may, if necessary in relation to review, invite relevant experts with professional knowledge and experience and hear their opinions.

⑤ Matters necessary for the composition and operation of the central review board other than those specified in paragraphs 1 through 4 shall be determined and notified by the Minister of Ministry of Food and Drug Safety.

[newly established on July 21, 2022]

Article 39 (Application for Conditional License, etc.)

(1) A person who intends to obtain conditional manufacturing business license pursuant to Article 35 (1) of the Act shall submit a conditional license application form provided in the Form No. 1 (including an electronic format) together with documents pursuant to Article 2 (1) subparagraph 1 and documents of each of the following subparagraphs (including electronic documents) to the Commissioner of the Regional FDS. In this case, the Commissioner of the Regional FDS shall check a certified copy of corporation register (applicable to corporations only), a certified copy of land register and a certified copy of building register through common use of administrative information pursuant to Article 36 (1) of the Electronic Government Act.

1. Document which confirms ownership of land in cases where buildings will be newly built (attached document may not be submitted in cases where it is possible to confirm with a certified copy of land register);
2. Document which confirms ownership of building in cases where existing buildings will be used

(attached document may not be submitted in cases where it is possible to confirm with a certified copy of building register) or a rental contract.

(2) Products to obtain conditional marketing approval of manufacture and sale pursuant to Article 35 (1) of the Act shall be products which require new facilities.

(3) A person who intends to obtain conditional marketing approval of manufacture and sales pursuant to Article 35 (1) of the Act shall submit an application form provided in the Form No. 4 (including an electronic format) together with documents pursuant to Article 4 (1) and documents pursuant to paragraph (1), subparagraphs 1 and 2, if necessary, to the Minister of Ministry of Food and Drug Safety. In this case, the Minister of Ministry of Food and Drug Safety shall check a certified copy of land register and a certified copy of building register through common use of administrative information pursuant to Article 36 (1) of the Electronic Government Act.

(4) A person who intends to apply for conditional license or approval shall pay a fee as announced by the Minister of Ministry of Food and Drug Safety.

Article 39-2 (Application for Conditional Approval of Items, etc.) (1) "Drugs prescribed by the Ordinance of the Prime Minister" in the part other than each subparagraph of Article 35 (2) of the Act refers to drugs falling under any of the following subparagraphs:

1. Medicines intended to treat serious diseases such as life-threatening cancer

2. Orphan drugs

② A person who intends to obtain conditional approval for pharmaceutical items pursuant to Article 35 (2) of the Act shall submit an application for conditional approval for manufacturing, sales and importation of pharmaceuticals in Attachment writing form 4 to the Minister of Ministry of Food and Drug Safety with the following documents attached.

1. Documents proving that it falls under any of the subparagraphs of Article 35 (2) of the Act
2. Documents under each subparagraph of Article 4 (1) (except for data on clinical trial results under Article 9 (6) among the documents under Article 4 (1) 1)

③ Notwithstanding paragraph 2, if it falls under any of the subparagraphs

of Article 4, paragraph 2, data for that category may not be submitted.

④ "Clinical evaluation variables prescribed by the Ordinance of the Prime Minister" in Article 35 (2) 1 of the Act refers to clinical evaluation variables that can objectively identify clinical benefits or efficacy and effects for diseases or disorders.

⑤ A person who applies for conditional approval of pharmaceutical items pursuant to Paragraph 2 shall pay a fee determined and publicly notified by the Minister of Ministry of Food and Drug Safety.

[newly established on July 21, 2022]

Article 40 (Execution of Conditions) (1) When a person who has obtained conditional approval for a pharmaceutical manufacturing facility or conditional approval for a drug manufacturing and sales item facility pursuant to Article 35 (1) of the Act has a facility suitable for Article 31 (1) of the Act, the fact shall be notified to the head of the regional office. <Amended on July 21, 2022>

(2) When the fulfillment of condition is notified pursuant to paragraph (1), the Commissioner of the Regional FDS shall confirm whether the condition is fulfilled within 20 days from the date of notification.

(3) A person who has obtained conditional approval for pharmaceutical items pursuant to Article 35 (2) of the Act shall report the implementation status of clinical trials subject users to the Minister of Ministry of Food and Drug Safety by March 31 of each year. <Newly established on July 21, 2022>

(4) A person who has obtained conditional approval for pharmaceutical items pursuant to Article 35 (2) of the Act shall complete the clinical trial subject users within a period separately determined by the Minister of Ministry of Food and Drug Safety, and then submit the relevant clinical trial report to the Minister of Ministry of Food and Drug Safety. <Newly established on July 21, 2022>

Article 40-2 (Designation of Priority Review) ① The criteria for designation of drugs subject to priority review under Article 35-4 Paragraph 1 of the Act are as follows:

1. It shall fall under any of the subparagraphs of Article 35-4 (2) of the Act;
2. The origin or discovery and development history, manufacturing method, or usage and dosage shall be reasonable and rational.
3. Efficacy and effect for the prevention and treatment of disease or illness shall be objectively and reasonably expected.

② A person who intends to designate a drug under development as a subject of priority review pursuant to Article 35-4 Paragraph 1 of the Act shall submit an application for designation of a drug subject to priority review in Attachment writing form No 40-4 attached the following documents which demonstrates that the form meets the criteria of the paragraph 1 of the Act.

1. Data proving that it falls under any of the subparagraphs of Article 35-4 (2) of the Act
2. Data on origin or discovery and development history
3. Data on manufacturing methods
4. Data on usage, dosage and efficacy and effectiveness

③ “Medicines prescribed by the Ordinance of the Prime Minister” under Article 35-4 Paragraph 2 Subparagraph 1 of the Act means medicines falling under any of the following subparagraphs.

1. Medicines with no substitutes
2. Drugs that have significantly improved or are expected to significantly improve safety and efficacy compared to alternative drugs

④ Minister of Ministry of Food and Drug Safety shall issue a letter of designation of drugs subject to priority review according to Form No. 40-5 to the applicant when designating a drug subject to priority review pursuant

to Article 35-4 Paragraph 3 of the Act.

⑤ The Minister of Ministry of Food and Drug Safety shall review the medicines designated for priority review pursuant to Article 35-4 Paragraph 3 of the Act within 90 days unless otherwise notified reasons.

⑥ Details on the preparation guidelines and requirements for attachments necessary for the application for designation of priority review subject under Paragraph 2 shall be determined and notified by the Minister of Ministry of Food and Drug Safety.

[newly established on January 20, 2022]

Article 41 (Scope of Prior Review, etc.)

(1) The scope of prior review under Article 35-2 (1) of the Act is as follows;

1. Information on safety and efficacy;
2. Information on specifications and test methods;
3. Information on production and quality control of medicinal products;
4. Information on clinical trial plan;
5. Deleted < Oct. 25, 2018>;
6. Information on pharmaceutical development plan;
7. Others needed for approval or register of medicinal products, approval of clinical trial plan or approval of bioequivalence study plan.

(2) A person who intends to apply for prior review of information as prescribed in paragraph (1) in accordance with Article 35-2 (1) of the Act shall submit to the Minister of Ministry of Food and Drug Safety the application for prior review of medicinal products of Form No. 41 (including electronic applications), together with the relevant documents (including electronic documents).

(3) The Minister of Ministry of Food and Drug Safety shall review the applications of paragraph (2) and issue the notification of prior review results of Form No. 42.

(4) A person who intends to apply for prior review pursuant to paragraph (2) shall pay the fee as notified by the Minister of Ministry of Food and Drug Safety.

(5) In addition to provisions of paragraphs (1) through (3), detailed scope of prior review, procedures, methods and others shall be announced by the Minister of Ministry of Food and Drug Safety.

Article 42 (Manufacturing Supervisors, etc.)

(1) Pursuant to Article 36 (1) of the Act, a manufacturer of medicinal products (excluding manufacturers of quasi-drug who manufacture only products falling under subparagraph 7 (a) of Article 2 of the Act) shall have manufacturing supervisor(s) as follows: However, the safety control manager under the High-Pressure Gas Safety Control Act may take the role of the manufacturing supervisor in Sub-paragraph 2 and manufacturing supervisor of portable products which temporally supply air or oxygen among quasi-drugs of the Subparagraph 3, Item E and the manufacturing supervisor under the Blood Management Act shall take the role of the manufacturing supervisor in Sub-paragraph 2, Item G.

<Revised on Aug. 21, 2014, January 4, 2017>

1. A manufacture of medicinal products which are directly applied to human bodies: more than 2 manufacturing supervisors;
2. A manufacturer of medicinal products falling into the following items: more than 1 manufacturing supervisor
   A. Medicinal products which are not directly applied to human bodies;
   B. Drug substances;
   C. Medicinal products manufactured only through subdivision;
   D. Radiopharmaceuticals;
   E. Medicinal gases;
   F. If all products are produced under contract;
   G. Blood products
3. A manufacturer of quasi-drugs: more than 1 manufacturing supervisor

(2) A person who is allowed to control manufacturing operations falling under the subparagraph 7 (a) of Article 2 of the Act shall be as follows: <Revised on Sep. 25, 2015, March 30, 2018>

1. A doctor, a pharmacist or a person who majored in science and engineering (meaning science and engineering pursuant to Article 2, Subparagraph 1 of the Special Act on Support of Scientists and Engineers for Strengthening National Science and Technology Competitiveness. The same shall apply hereinafter.) those who acquired degree more than bachelor's degree of the department, or those who are recognized as having an equivalent level of education pursuant to laws and regulations;
2. As a person who majored in non-science and engineering subject at a four-year college (including a person who is recognized as having an equivalent level of education pursuant to laws and regulations), a person who has engaged in the quasi-drugs manufacturing business for at least 2 years(including careers prior to graduation or education recognition);
3. As a person who has graduated from a science and engineering department at a junior college with a three-year term of study pursuant to Article 48 of the Higher Education Act (including a person who is recognized as having an equivalent level of education pursuant to laws and regulations), a person who has engaged in the quasi-drugs manufacturing business for at least one year(including careers prior to graduation or education recognition);

3-2. As a person who has graduated from a science and engineering department at a junior college with a two-year term of study pursuant to Article 48 of the Higher Education Act (including a person who is recognized as having an equivalent level of education pursuant to laws and regulations), a person who has engaged in the quasi-drugs manufacturing business for at least two years(including careers prior to graduation or education recognition);

4. As a person who has graduated from a department other than a science and engineering department at a junior college (including a person who is recognized as having an equivalent level of education pursuant to laws and regulations), a person who has engaged in the quasi-drugs manufacturing business for 3 at least years(including careers prior to graduation or education recognition);

5. As a high school graduate pursuant to the Elementary and Secondary Education Act, a person who has engaged in the quasi-drugs manufacturing business for at least 4 years.

(3) A person who intends to obtain an approval as the manufacturing supervisor of biological products, cellular therapy products, gene therapy products, or quasi-drugs pursuant to proviso to the main part of Article 36 (1) or Article 36 (2) of the Act shall submit an application form for the manufacturing supervisor provided in the Form No. 43 (including an electronic format) together with documents which prove the relevant qualification (including electronic documents) to the Commissioner of the Regional FDS and when the qualification is acknowledged, the Commissioner of the Regional FDS shall put an approval on the register of approval and issue a certificate of approval provided in the Form No. 44. <Revised on Sep. 25, 2015>

(4) When a manufacturer of medicinal products, etc. has two or more manufacturing supervisors pursuant to Article 36 (1) and (2) of the Act, the duties shall be divided and the lines of responsibility shall be clearly established.

(5) When a manufacturer of medicinal products intends to have the manufacturing supervisor pursuant to Article 36 (1) and (2) of the Act, a manufacturer of medicinal products shall submit a report form of the manufacturing supervisor provided in the Form No. 45 (including an electronic format) together with documents of each of the following subparagraphs to the Commissioner of the Regional FDS. In cases where a manufacturing business license of medicinal products is applied for approval or reported pursuant to Article 2 (1), a report form of the manufacturing supervisor provided in the Form No. 45 may not be submitted.

1. A document which confirms the qualification of the manufacturing supervisor or a certificate of approval pursuant to paragraph (3);
2. A certificate of approval or a certificate of register(case issued in electronic form is not included respectively).

(6) When the Commissioner of the Regional FDS accept a report of the manufacturing supervisor pursuant to paragraph (5), he/she shall verify the license of pharmacist through the procedure for common use of administrative information in accordance with Article 36 (1) of the Electronic Government Act: Provided, That, if the applicant does not consent to such verification, copies should be attached.

(7) When the Commissioner of the Regional FDS accept a report of the manufacturing supervisor pursuant to paragraph (5), he/she shall notify it to the Minister of Ministry of Food and Drug Safety, and the acceptance of report shall be put on the register of approval.

(8) A person who intends to apply for an approval as the manufacturing supervisor pursuant to paragraph (3) shall pay a fee as prescribed and announced by the Minister of Ministry of Food and Drug Safety.

(9) The " professional with bacteriological knowledge prescribed by Ordinance of the Prime Minister" referred to in proviso to Article 36 (1) of the Act shall means a person who has graduated from a biochemistry, microbiology, biotechnology, veterinary science or related department at a four-year college (including universities higher than four-year colleges). <Newly established, Sep. 25, 2015>

Article 43 (Matters to be Observed by Manufacturing Supervisor)

(1) Matters to be observed by the manufacturing supervisor of medicinal products, etc. pursuant to Article 37 (1) of the Act shall be as the following subparagraphs:

1. To manage manufacturing facilities in a sanitary way and to prevent the intrusion of insects, cross-contamination or contamination from outside;
2. To check sanitary condition of personnel strictly and to concentrate on training and supervision in order to produce quality medicinal products, etc.;
3. To manufacture products precisely according to Standard Operating Procedures for Production Control, Product Master File (Master Formulae), etc.;
4. To make sure no potentially hazardous materials exist in production areas and no harmful materials spill or release in and out of production areas;
5. To thoroughly perform required tests and examination from the receipt of raw materials and materials to the release of finished products, to prepare batch production records and quality control records on each batch and to retain them for three years or more from the manufacturing date;
6. When using organic solvents during manufacturing process, to strictly manage by establishing the standards for kinds, specifications, purpose of use, the amount to be used, the amount of residue, etc. of organic solvents;

(2) When the manufacturing supervisor gets no longer engaged in the management of the manufacturing site, it shall be promptly reported to the Commissioner of the Regional FDS in the Form No. 46 (including electronic document), together with explanatory statement (including electronic document). <Revised on Oct. 28, 2016>

Article 44 (The Contents, Amount of Time, Methods, etc. of Training of Manufacturing Supervisor)

(1) The contents of training pursuant to Article 37-2 (1) of the Act refers to legislation, systems and technology necessary for securing safety and efficacy of medicinal products, etc., and for manufacture and quality control of medicinal products, etc., and shall be prescribed by the Minister of Ministry of Food and Drug Safety.

(2) The amount of time of training shall be 16 hours or more for two years.

(3) Training institutions pursuant to Article 37-2 (4) (hereinafter referred to as "training institutions") shall establish and submit training plan including target and the contents of training for the following year and submit it until Dec. 10 every year to the Minister of Ministry of Food and Drug Safety.

(4) Training institutions shall issue a certificate to a person who completes the training course and write down the relevant matters such as a list of those who complete the training course and archive those documents for two years.

(5) Training institutions shall report to the Minister of Ministry of Food and Drug Safety of the documents concerning the training in the previous year until January 31 every year.

(6) Matters such as the content, amount of time, methods and procedures of training which are necessary for training of manufacturing supervisors other than those prescribed in paragraphs (1) to (5) shall be determined and announced by the Minister of Ministry of Food and Drug Safety.

Article 45 (Designation, Cancellation of Designation, etc. of Manufacturing Supervisor Training Institutions)

(1) The Minister of Ministry of Food and Drug Safety may designate one of the following organizations or institutions as training institutions (hereinafter referred to as "training institutions") in accordance with Article 37-2 (4) of the Act.

1. Pharmaceutical affairs organizations under Article 67 of the Act;
2. Other specialized organizations or institutions related to medicinal products, etc.

(2) A person who intends to apply for designation of training center shall submit to the Minister of Ministry of Food and Drug Safety the application for designation of manufacturing supervisors training institution of Form No. 47 (including an electronic document), together with the following documents and information (including electronic documents).

1. Training organization and personnel;
2. Training facilities and equipment;
3. Evidentiary materials on calculation of tuition fee;
4. Enforcement regulation on training; and
5. Implementation plan for training.

(3) On receipt of the application under paragraph (2), the Minister of Ministry of Food and Drug Safety may conduct investigation to verify if the contents of application satisfy the requirements for designation.

(4) When designating a training institution, the Minister of Ministry of Food and Drug Safety shall issue the certificate of designation of manufacturing supervisors training institution for medicinal products, etc. of Form No. 48 and notify the information on such designation of training center, including the name, address and representative.

(5) The training institution may receive tuition fees from trainees while considering costs for training materials, on-site practical exercise and lecturers. In such instance, the tuition fee shall be determined by the head of the training center on the basis of actual expenses. <Revised on Sep. 25, 2015>

(6) The Minister of Ministry of Food and Drug Safety may revoke the designation of a manufacturing supervisor training institution which is given pursuant to Paragraph (4) if any of the following is applicable. However, if Subparagraph 1, 2 or 6 is applicable, the designation shall be canceled. <Newly

established, Oct. 28, 2016>

1. If the designation is given through false or illegal methods;
2. If a certificate is issued to a person who has not completed the education pursuant to Article 37-2 (1) to (3) of the Act;
3. If the educational plan has not been submitted pursuant to Article 44 (3);
4. Failure to issue a certificate or to keep records of conducting training pursuant to Article 44 (4);
5. Failure to report the implementation of training pursuant to Article 44 (5);
6. Failure to provide education in accordance with the plan to conduct training pursuant to Article 44 (3) without proper cause or to operate the training program for more than one year.

(7) In addition to the matters prescribed in paragraphs (1) to (5), the details of the designation, management, etc. of the institution conducting training of manufacturing managers shall be prescribed and notified by the Minister of Ministry of Food and Drug Safety. <Revised on Oct. 28, 2016>

[Title Revised on Oct. 28, 2016]

Article 46 (Safety Control Manager, etc.)

(1) A marketing authorization holder shall appoint one or more safety control managers in accordance with Article 37-3 of the Act: Provided, That in case when a marketing authorization holder only for blood derivatives, herbal substances, drug substances, medical high-pressure gas, or products that are not directly applied to humans, safety control managers may not be required. <Revised on May 9, 2014, June 30, 2016, January 4, 2017>

(2) If there are more than two safety control managers under paragraph (1), their roles and responsibilities shall be clearly defined.

(3) When it is intended to have the safety control manager pursuant to paragraph (1), the safety control manager report of Form No. 49 (including an electronic report) shall be submitted to the Commissioner of the Regional FDS, together with the following documents (including electronic documents). In such instance, on receipt of the report, the Commissioner of the Regional FDS shall verify the license of pharmacist (limiting to cases where the safety control manager is a pharmacist) through the procedure for common use of administrative information in accordance with Article 36 (1) of the Electronic Government Act and, if the reporter does not allow to verify his/her license through the common use of administrative information, he/she shall be required to submit a copy of the license of pharmacist.

1. Documents showing qualifications of safety control manager;
2. Certificates of medicinal products manufacturing business license or certificates of contract manufacture and marketing declaration(A case tha electronic document is issued is excluded respectively).

(4) When the Commissioner of the Regional FDS accepts the safety control manager declaration under paragraph (3), the Commissioner of the Regional FDS shall notify such acceptance to the Minister of

Ministry of Food and Drug Safety.

Article 47 (Responsibilities of Safety Control Manager)

(1) The safety control manager shall have the following responsibilities in accordance with Article 37-3 (2) of the Act. <Revised on Aug. 21, 2014, Oct. 28, 2016>

1. The safety control manager shall strictly perform safety control affairs after releasing such as renewal of marketing approval and notification of manufacture and sales of medicinal products and re-examination of new drugs, etc., information management, etc. of safety of medicinal products.
2. The safety control manager shall not involve in jobs, such as sale of medicinal products, that may adversely affect his/her drug safety management.
3. The safety control manager shall observe the standards of safety control affairs regarding matters falling under the following items determined and announced by the Minister of Ministry of Food and Drug Safety.
   A. Matters regarding collection of information on safety of medicinal products;
   B. Analysis and evaluation of information collected under item A and initiation of safety control actions on the basis of such analysis and evaluation;
   C. Reporting and communication of information on safety of medicinal products;
   D. Training of persons who perform safety control affairs and other necessary for safety of other medicinal products;
   E. Matters concerning the implementation of the risk management plan pursuant to Subparagraphs 8 of the post-marketing safety control standards for medicinal products, etc. in Annex 4-3.
4. The safety control manager shall write a report about the post-marketing safety control work pursuant to Article 37-3 (1) of the Act and keep it for at least 3 years from the date on which the action is completed.
5. The safety control manager shall fulfill the following requirements in connection with the risk management plan (limited to medicinal products for which risk management plans were submitted).
   A. To prepare the risk management plan as notified by the Minister of Ministry of Food and Drug Safety and execute such plan;
   B. To record the fact of executing the risk management plan under the subparagraph A;
   C. To maintain records of the subparagraph B for at least 3 years from date of execution of the risk management plan;
   D. To propose the change of risk management plan to the person who has been granted the authorization of manufacture, sales and importation of medicinal products, if the change of the risk management plan is deemed necessary.

(2) If a safety control manager is not engaged in safety control at the relevant manufacturing site or business office, he/she shall submit to the Commissioner of the Regional FDS the non-engagement

declaration of Form No. 46 (including an electronic declaration), together with the letter of explanation thereof (including an electronic document) without delay. <Revised on Oct. 28, 2016>

Article 47-2 (Contents, Time, Methods, etc. of Training for Safety Control Manager)

(1) Contents of training pursuant to Article 37-4 (1) and (2) of the Act shall be in legal requirements, systems and techniques, etc. that are needed for post-marketing safety control work such as the re-examination of new drugs, etc., re-evaluation of medicinal products, and reporting of adverse effects.

(2) Training under Article 37-4 (1) of the Act shall be conducted every 2 years, and training hours shall be no less than 16 hours.

(3) Each year, the training institutions that have been designated pursuant to Article 37-4 (4) of the Act (hereinafter referred to as "training institutions for safety control managers") shall develop a training plan including trainees, contents of the training, etc. for the following year; submit it to the Minister of Ministry of Food and Drug Safety by November 30; and obtain approval. This requirement shall equally apply when intending to make changes to the matters that have been approved.

(4) The training institution for safety control managers shall issue certificates to persons who have completed the training, record information on training such as the list of persons who have completed the training, and maintain such records for 2 years from the date of recording.

(5) The training institution for safety control managers shall submit a report on previous year’s training, including a list of persons who have completed the training, etc. to the Minister of Ministry of Food and Drug Safety by January 31 of the following year.

(6) The training institutions for safety control managers may receive training fees from trainees considering the expenses needed for training such as training materials, practical exercises, instructor’s wages, etc. In this case, the training fees shall be determined on the basis of actual expenses by the head of the training institutions for safety control managers.

(7) In addition to matters prescribed in the paragraphs (1) to (6), detailed requirements such as the contents, methods, procedures, etc. of the training for safety control managers shall be determined and notified by the Minister of Ministry of Food and Drug Safety.

[This Article is newly established. Oct. 10, 2014]

Article 47-3 (Designation and Cancellation of Safety Control Manager Training Institutions)

(1) The Minister of Ministry of Food and Drug Safety may designate one of the following organizations or institutions as the safety control manager training institution in accordance with Article 37-4, Paragraph (4) of the Act.

1. Pharmaceutical industry organization under Article 67 of the Act;
2. Other professional organizations or institutions relating to medicinal products.

(2) A person who intends to be designated as the safety control manager training institution shall submit to the Minister of Ministry of Food and Drug Safety the application for designation of safety control

manager training institution provided in Form No. 83 (including an electronic application) and the following documents and information (including electronic documents).

1. Information on organization and personnel for operation of training programs;
2. Information on training facilities and equipment;
3. Information on calculation of training fees;
4. Training procedures and plan.

(3) The Minister of Ministry of Food and Drug Safety may, on receipt of the application of paragraph (2), inspect the training facilities, equipment and other of the organization or institution intending to be designated as the safety control manager training institution.

(4) The Minister of Ministry of Food and Drug Safety shall, on designation of the safety control manager training institution, issue the certificate of designation of safety control manager training institution provided in Form No. 84 to the applicant.

(5) A safety control manager training institution which intends to apply for amendment of the certificate issued in paragraph (4) shall submit the Minister of Ministry of Food and Drug Safety the application for amendment to designation of safety control manager training institution provided in Form No. 83 (including an electronic application), together with a statement of reasons and supporting documents within 30 days after the date when the reason for amendment occurs.

(6) The Minister of Ministry of Food and Drug Safety shall, on approval of such amendment, describe such changes in the certificate of designation of safety control manager training institution.

(7) The Minister of Ministry of Food and Drug Safety shall, on designation or amendment to designation of safety control manager training institutions under provisions of paragraph (4) or (6), make a public announcement of such designation or amendment to designation of a safety control manager training institution, including the name, address and representative.

(8) If a training institution for safety control managers designated pursuant to the Paragraph (4) falls into one of the following subparagraphs, the Minister of Ministry of Food and Drug Safety may cancel such designation. However, if Subparagraph 1, 2 or 6 is applicable, the Minister of Ministry of Food and Drug Safety shall cancel such designation:

1. If the designation is given through false or illegal methods;
2. If a certificate was issued to a person who did not complete the training pursuant to Article 37-4 (1) and (2) of the Act;
3. Failure to submit a training plan or to get approval or approval of change pursuant to Article 47-2 (3);
4. Failure to issue a certificate or to maintain records of conducting trainings pursuant to Article 47-2 (4);
5. Failure to report records of conducting trainings pursuant to Article 47-2 (5);
6. Failure to conduct training according to the training plan under Article 47-3 (2) or to operate a training program for at least one year without justifiable reason;

7. Failure to submit an application for changes to the matters that have been designated pursuant to Article 47-3 (5).

(9) In addition to the matters prescribed in paragraphs (1) to (7), detailed requirements for designation, operation, etc. of training institutions for safety control managers shall be determined and notified by the Minister of Ministry of Food and Drug Safety.

[This Article is newly established. Sep. 25, 2015]

Article 48 (Duties of Compliance for Manufacturer, etc.)

Pursuant to Article 37-3 (1) and Article 38 (1) of the Act, matters to be observed by a person who is a manufacturer of medicinal products, etc. or who has obtained marketing approval of medicinal product shall be subparagraphs of Article 43 (1) and the following subparagraphs: <Revised on May 9, 2014, Aug. 21, 2014, Oct. 28, 2016>

1. Perform thoroughly quality test of medicinal products, etc. and release the approved products only;
2. For sterile medicinal products, make sure that only new containers shall be used;
3. When obtaining new data related to safety and efficacy of approved or registered products or information, etc. (including cases of side effects caused by using medicinal products, etc.) and conducting an investigation to collect, analyze and evaluate the information regarding safety and efficacy, make a report and take proper measures pursuant to subparagraphs 6 to 8 of the post-marketing safety control standards for medicinal products, etc. in Annex 4-3;
4. In case when using a measuring cup or a spoon, etc. other than medicinal device pursuant to the Medicinal Device Act to pediatric medicinal products prescribed by the Minister of Ministry of Food and Drug Safety (hereinafter referred to as "pediatric medicinal product"), use a measuring cup or a spoon which satisfy the requirements prescribed by the Minister of Ministry of Food and Drug Safety;
5. Sell medicinal products which are manufactured in compliance with the standards falling under the following items:

A. For drug products, sell the products which are manufactured within the expiration date of conformity dtermination(it refers to conformity under the Article 48-2 paragraph 1. Hereinafter the same shall applies in this Article). In such case, among drugs manufactured for the purpose of evaluation to receive conformity, a drug determined to meet the criteria of Annex 1 shall be considered to be manufactured after the decision is made that they are in compliance with the standard referred to in Annex 1.

B. Drug substances (raw drug substances without herbal medicines and pharmacological activity, and those used in other products that are not directly applied to the human body are excluded. Hereinafter, the same applies in this Article 48-2 and Article 48-3): sell what was manufactured within the expiration period of conformity determination. In this case, among drug substances manufactured for the purpose of

evaluation to receive conformity, drugs determined to meet the criteria in Annex Table 1-2 shall be deemed manufactured after receiving conformity determination.

C. For biological products(except for the blood pharmaceuticals. the same applies in this Article 48-2 and Article 48-3). sell what was manufactured within the expiration period of conformity determination. In this case, among biological products manufactured for the purpose of evaluation to receive conformity, bilogical products determined to meet the criteria in Annex 1, Annex 1-2, 3 shall be deemed manufactured after receiving conformity determination.

D. For radio pharmaceuticals: sell radio pharmaceuticals manufactured within the expiration period of conformity. In such case, among radiopharmaceuticals manufactured with the purpose of evaluation to receive conformity and those determined to meet the criteria referred to in Annex 1, Annex 1-2, and Annex 3-2 shall be shall be deemed manufactured after conformity determination.

E. For medical high-pressure gas (excluding disinfectant products not directly applied to the human body, products specified and notified by the Minister of Ministry of Food and Drug Safety are excluded. Hereinafter, the same applies in this Article, Article 48-2 and Article 48-3): Sell what was manufactured within the validity period of the conformity determination . In this case, among medical high-pressure gases manufactured for the purpose of evaluation to obtain conformity, medical high-pressure gases determined to meet the criteria in Annex 1, Annex 1-2, and Annex 3-3 shall be deemed manufactured after conformity determination.

F. Herbal medicinal materials: To sell products manufactured within the validity period of conformity determination. In this case, among herbal medicines manufactured for the purpose of evaluation to receive conformity determination, herbal medicines determined to meet the criteria in Annex 2 shall be deemed manufactured after receiving conformity determination.

G. For blood products: Sell (supply) those manufactured within the validity period of the conformity determination. In this case, among blood products manufactured for the purpose of evaluation to receive a conformity determination, blood products determined to meet the criteria in Annex 3-4 shall be deemed manufactured after receiving a conformity determination.

5-2. In the case in which the manufactures of aseptic preparation[and etc. manufacturers of work places which have to follow the criteria of aseptic pharmaceutical of the subparagraph 1 of the Article 7 (1) of 「Enforcement regulation of the decree of standard of facilities of manufacturer and importer of pharmaceuticals」and the subparagraph 2 of the Article 7 of the same regulation (work places according to the subparagraph of the of the Article 3 (1) of「Decree on stadard on facilities of manufacturer and importer of pharmaceuticals」hereinafter referred to as th same below.) change important matters determined and notified by the Minister of Food and Drug Safety such as

building · rebuilding · extending · reconstruction and replacing of air conditioning equipment and etc., they shall manufacture pharmaceuticals after receiving the determination that pharmaceuticals meet the criteria according to the classification of each Item of the Subparagraph 5(including the evaluation of the implementation situation).

6. A manufacturer of quasi-drugs, when manufacturing oral solids, oral liquids and external ointments and cataplasma products complying with standard manufacturing requirements as notified by the Minister of Ministry of Food and Drug Safety, shall sell quasi-drugs which are manufactured after the decision that the products are in compliance with Good Manufacturing Practice for Medicinal Products of Annex 1 is made. In such case, among quasi-drugs manufactured with the purpose of evaluation of GMP operation of medicinal products of Annex 1, those decided to meet the standards referred to in Annex 1 shall be considered to be manufactured after the decision is made that they are in compliance with the standard referred to in Annex 1.
7. Not to manufacture a medicinal product which proves to infringe other's patent rights;
8. Not to store medicinal products in the place other than approved manufacturing sites pursuant to Article 31 (1) of the Act (including business offices pursuant to Article 6);
9. A medicinal product manufacturer shall comply with Good Manufacturing Practice regulations as follows:
   A. A manufacturer of drug products [except those having no direct effect in humans (disinfectants, etc.)]: GMP for Medicinal Products in Annex 1;
   B. Drug Substance Manufacturers: GMP for Drug Substances in Annex 1-2;
   C. Manufacturers of Biologicals, etc.: GMP in Annex 1, GMP for Drug Substances in Annex 1-2, and GMP for Biologicals, etc. in Annex 3;
   D. A manufacturer of radiopharmaceuticals: GMP for Medicinal Products in Annex 1, GMP for drug Substances in Annex 1-2, and GMP for Radiopharmaceuticals in Annex 3-2;
   E. Medical high-pressure gas manufacturers (excluding disinfectant products that are not directly applied to the human body, products determined and notified by the Minister of Ministry of Food and Drug Safety are excluded): GMP for pharmaceuticals in Annex 1, GMP for Drug Substances in Annex 1-2 and GMP for Medical High-Pressure Gas in Annex 3-3
   F. A manufacturer of herbal substances: GMP for Herbal Substances in Annex 2.
   G. Blood product manufacturers: GMP for blood product in Annex 3-4

   9-2. A quasi-drug (limiting to oral solids, oral liquids and external ointments and cataplasma products complying with standard manufacturing requirements as notified by the Minister of Ministry of Food and Drug Safety) manufacturer shall comply with GMP for Medicinal Products in Annex 1.

10. Deleted <Sep. 25, 2015>
11. A manufacturer of plasma derivatives shall conform to the Standards for Source Plasma Management of Annex 5.
12. A manufacturer of plasma derivatives shall use plasma collected in Korea on the preferential basis when manufacturing plasma derivatives: Provided, that this shall not apply when deemed by the Minister of Ministry of Food and Drug Safety that the shortage of plasma derivatives is expected.
13. In case where a manufacturer of medicinal products, etc. intends to manufacture medicinal products, etc. by using drug substances subject to registration, the product falling under only one of the following subparagraphs:
    A. Drug substances notified on Internet by the Minister of Ministry of Food and Drug Safety pursuant to the latter part other than each subparagraph of Article 16;
    B. Drug substances that a manufacturer oneself has submitted documents falling under items of Article 4 (1) 7 pursuant to provisos other than every item of Article 4 (1) 7 or Article 5 (2) 6 when the manufacturer obtains marketing approval or notification of manufacture and sale pursuant Article 4 (1) or Article 5 (2).
14. Observe matters ordered by the Minister of Ministry of Food and Drug Safety, concerning data submission, inspection, manufacturing and quality control, labelling, etc. necessary for safety and efficacy of medicinal products, etc.
15. A person who has appointed by the Minister of Ministry of Food and Drug Safety shall manufacture and supply small unit packaged products such as blister packs as prescribed by the Minister of Ministry of Food and Drug Safety. In this case, the small unit package of non-prescription drugs shall be 10 tablets or more, excluding the case the smaller unit is necessary due to the property of the over-the-counter drug.
16. Over-the-counter drugs shall be supplied in one-day package: Provided, In case where the Minister of Health and Welfare determines alternative ways while considering single dose, daily administration frequency, dosage form and information indicated on external packaging materials and determines to change the package unit, that shall be followed.
17. A manufacturer of cigarette type -smoking cessation aids among quasi-drugs shall have the products in compliance with the acceptable standards, acceptable error range and measuring standards of tar, nicotine and carbon monoxide as prescribed by the Minister of Ministry of Food and Drug Safety and shall request a measurement agency designated by the Minister of Strategy and Finance to measure tar, nicotine and carbon monoxide of products on sale within one month after the first day of every quarter pursuant to Article 25-2 of the Tobacco Business Act and shall archive the result thereof for three years or more from the date of measurement.
18. Pursuant to subparagraph 5 of Article 62, among herbal medicines designated as herbal medicine subject to standardized products, matters regarding properties, conditions, quality and storage methods, etc. of herbal medicines determined and announced by the Minister of Ministry of Food

and Drug Safety shall be observed.

19. Not to sell medicinal products of which marketing approval or notification of manufacture and sale is expired.
20. Carry out the risk management plan to assure safe use of medicinal products (limited to medicinal products for which risk management plans were submitted).
21. Gather and evaluate safety information on medicinal products and conduct post-marketing safety control such as establishment, etc. of proper safety measures pursuant to the post-marketing safety control standards for medicinal products, etc.

Article 48-2 (Determination of Conformity for GMP) (1) In accordance with Article 38-2 (1) of the Act, if a manufacturer of pharmaceuticals, etc. manufactures and sells pharmaceuticals, etc., the manufacturer shall receive a determination that the GMP for each of the following subparagraphs shall be met by the head of regional office of Food and Drug Safety(hereinafter referred to as "Determination of conformity"). <Amended on Dec 29, 2022>

1. Finished drugs: GMP for Pharmaceutical in Annex 1. In this case, among solid dosage forms for internal use, injections, eye drops, solutions for internal use, solutions for external use, ointments, and dosage forms belonging to other dosage form groups, each dosage form determined and notified by the Minister of Ministry of Food and Drug Safety shall receive determination of conformity.
2. Drug substances: GMP for drug substances in Annex 1-2. In this case, it is necessary to receive a determination of conformity for each synthesis, fermentation, extraction, purification, and other manufacturing method.
3. Biological products, etc.: GMP for Pharmaceutical in Annex 1, GMP for drug substance in Annex 1-2, and GMP for biological products, etc. in Annex 3
4. Radio pharmaceuticals: GMP for pharmaceutical in Annex 1, GMP for drug substance in Annex 1-2 and GMP for radio pharmaceutical in Annex 3-2
5. Medical high-pressure gas: GMP for Pharmaceutical in Annex 1, GMP for drug substance in Annex 1-2 and GMP for Medical High Pressure Gas in Annex 3-3
6. Herbal medicines: GMP for herbal medicines in Annex 2
7. Blood products:GMP for blood product in Annex 3-4
8. Quasi-drugs (limited to solid dosage forms for internal use, liquid formulations for internal use and external skin ointments and cataplasma formulations that meet the standard manufacturing criteria for drugs notified by the Minister of Ministry of Food and Drug Safety): GMP for Pharmaceutical in Annex 1. In this case, a determination of conformity shall be obtained for each dosage form.

② Pharmaceutical manufacturers who intend to receive determination of conformity for each dosage form or manufacturing method pursuant to Paragraph 1 shall submit the application of determination of conformity of GMP for Pharmaceutical in Annex Form 81 (for drug substance manufacturers, it means application of

determination of conformity of GMP for drug substance, for herbal medicine manufacturers, it refers to the application determination of conformity of GMP for herbal medicine) attached the document following any subparagraph the head of regional office of Food and Drug Safety <Newly established on Dec 29, 2022>

1. In the case of drug manufacturers falling under paragraph (1) 1, 3 through 5, and 7

A. Floor plan of the manufacturing facility(including workroom, testing rooms, storage rooms, and other auxiliary facilities necessary for the manufacturing process) workroomfacility-related data that falls under the following

1) workroomfloor plan showing cleanliness level, differential pressure (pressure difference) in the workroom, and human and material movement flow

2) Machinery/equipment details and layout drawing used for manufacturing/testing

3) Air conditioning facility, compressed air and water treatment system diagram

C. Manufacturing facility and environmental management related data (including data on management status such as manufacturing water, cleanliness, and automation equipment)

D. Data related to organization chart and manufacturing/quality (assurance) system in accordance with GMP for pharmaceutical

E. Document management regulations and document list under GMP for pharmaceutical

F. Copies of master fomula, production and control record, and quality control records for the drugs for which conformity determination has been applied

G. Copies of master fomula, production and control record, and quality control records for drugs with the highest production performance in the previous year by dosage form group (if the drug is a biological product, etc., the drug with the highest production performance in the previous year by type of biological product, etc. is applicable to) (it is applicable only if there is production performance in the previous year of the dosage form that was determined conformity among the groups)

H. Validation data of drugs for which conformity determination has been applied and drugs with the highest production performance in the previous year by drug and dosage form group(if the drug is a biological product, etc., the drug with the highest production performance in the previous year by type of biological product, etc. is applicable to).

I. Other data deemed necessary by the head of regional office of Food and Drug Safety for the determination of conformity

2. In case of drug substance manufacturers

A. Data falling under subparagraph 1 (a) through (c)

B. Data related to organization chart and manufacturing/quality (assurance) system in accordance with GMP for drug substance

C. Document management regulations and document list under GMP for drug substances

D. Copies of master fomula, production and control record, and quality control records for the drugs for which

conformity determination has been applied

E.Copies of master fomula, production and control record, and quality control records for drugs with the highest production performance in the previous year by dosage form group (it is applicable only if there is production performance in the previous year of the dosage form that was determined conformity among the groups)

F. Validation data of drugs for which conformity determination has been applied and drugs with the highest production performance in the previous year by drug and dosage form group(it is applicable only if there is production performance in the previous year of the dosage form that was determined conformity among the groups)

G. Other data deemed necessary by the head of regional office of Food and Drug Safety for the determination of conformity

3. In case of herbal medicine manufacturers

A. Data falling under subparagraph 1 (a)

B. Workroom facility-related data that falls under the following

1) workroom floor plan showing human and material movement flow

2) Machinery/equipment details and layout drawing used for manufacturing/testing

C. Manufacturing facility and environmental management related data (including data on management status such as manufacturing water, cleanliness, and automation equipment)

D. Data related to organization chart and manufacturing/quality (assurance) system in accordance with GMP for herbal medicine

E. Document management regulations and document list under GMP for herbal medicine

F. Copies of master fomula, production and control record, and quality control records for the herbal medicine for which conformity determination has been applied

G. Copies of master fomula, production and control record, and quality control records for herbal medicine with the highest production performance in the previous year(it is applicable only if there is production performance in the previous year of the herbal medicine that was determined conformity)

H. Other data deemed necessary by the head of regional office of Food and Drug Safety for the determination of conformity

③ Manufacturers of quasi-drugs who intend to receive conformity determination for each dosage form in accordance with Paragraph 1 shall submit the application for conformity determination of quasi-drug GMP in Form No. 82-3 attached the document following any subparagraph to the head of regional office of Food and Drug Safety <Amended 2022. 12. 29.>

1. Data falling under paragraph (2) 1 (a) through (e)

2. Copies of master fomula, production and control record, and quality control records for quasi-drugs applied for conformity determination

3. Copies of master fomula, production and control record, and quality control records for quasi-drugs with the highest production performance in the previous year for each dosage form (applicable only if there is

production performance in the previous year of the dosage form for which conformity was determined)

4. Validation data for quasi-drugs for which conformity determination has been applied and quasi-drugs with the highest production performance in the previous year for each dosage form (only applicable where there is production performance of the conformity-determined dosage form in the previous year)

5. Other data deemed necessary for the determination of conformity by the head of the regional office

④ The head of a regional office may conduct a on-site inspection to evaluate whether the contents of the application conform to GMP for pharmaceuticals, etc. in case of receiving an application under paragraph 2 or 3. <Amended 2022. 12. 29.>

⑤ After reviewing the application form, in accordance with Paragraph 1, it is determined that the pharmaceuticals, etc. conform to the criteria of Annex 1, Annex 1-2, Annex 2, Annex 3, Annex 3-2, Annex 3-3 or Annex 3-4, shall issue a certificate of conformity according to the classification of each of the following subparagraphs. <Amended 2022. 12. 29.>

1. Medicines (herbal medicines are excluded): Form 81-2 of Annex 81, GMP for Pharmaceutical Conformity Determination

2. Herbal medicine: Certificate of conformity for GMP for herbal medicines in Form No. 82-4

3. Quasi-drugs: Certificate of Conformity for GMP for Quasi-drugs in Form No. 82-5

⑥ A person who files an application for conformity determination pursuant to paragraphs 2 and 3 shall pay a fee determined and notified by the Minister of Ministry of Food and Drug Safety. <Newly established 2022. 12. 29.>

⑦ The Minister of Ministry of Food and Drug Safety may establish and notify the GMP for quasi-drugs for which the practice under Annex 1 has not been established. <Newly established on 2022. 1. 20., 2022. 12. 29.>

⑧ If a manufacturer of quasi-drugs falling under paragraph 7 requests to determine conformity to the GMP determined and notified by the Minister of Ministry of Food and Drug Safety pursuant to the same paragraph, if appropriate, the head of a regional office of the Food and Drug Safety shall issue a conformity determination under the determined and notified by the Minister of Ministry of Food and Drug Safety, <Newly established 2022. 12. 29.>

⑨ In addition to the matters specified in paragraphs 1 through 8, details necessary for the procedure or method of determination of conformity shall be determined and notified by the Minister of Ministry of Food and Drug Safety. <Newly established 2022. 12. 29.>

[newly established on October 10, 2014]

[Title revision on Dec 29, 2022.]

Article 48-3 (Determination of Conformity for Changes in GMP for Pharmaceuticals, etc.) A pharmaceutical manufacturer who intends to receive a determination of conformity for changes under Article 38-2 (2) of the

provision shall submit an application for determination of conformity for changes for GMP for pharmaceutical(In case of drug substance manufacturers, it refers to the application form for change conformance of drug substance GMP in Attachment writing form No. 82, in case of herbal medicine, it refers to the application form for change conformance of herbal medicine GMP in attachment writing form 82(2)) to the head of the regional office of Food and Drug Safety attached a conformity determination certificate (cases issued in electronic form are excluded), a statement of reasons for change, and supporting documents (referring to documents under the classification of each subparagraph of Article 48-2 (2)).

② Manufacturers of quasi-drugs who intends to receive a conformity determination for changes according to Article 38-2 (2) of the Act shall submit an application for determination of conformity for changes for GMP for quasi-drug to the head of the regional office of Food and Drug Safety attached a conformity determination certificate (cases issued in electronic form are excluded), a statement of reasons for change, and supporting documents (referring to documents under the classification of each subparagraph of Article 48-2 (3)).

③ The head of a regional office may conduct a on-site inspection to evaluate whether the contents of the application meets GMP for pharmaceuticals, etc., when an application for conformity determination for the changes is received under paragraph (1) or (2).

④ The head of a regional office shall reissue reflecting the changes in the conformity certificate according to the classification of the following subparagraphs, if it is determined to meet the criteria specified in Annex 1, Annex 1-2, Annex 2, Annex 3, Annex 3-2, Annex 3-3 or Annex 3-4. after reviewing the application for determination of conformity for change pursuant to Paragraph 1 or 2.

1. Medicines (excluding herbal medicines): GMP for Pharmaceutical Conformity Determination of Form 81-2 of Annex 81
2. Herbal medicine: GMP for herbal medicines Certificate of conformity Determination of Form No. 82-4
3. Quasi-drugs: Certificate of Conformity Determination for GMP for Quasi-drugs in Form No. 82-5

⑤ A person who applies for a Conformity Determination under paragraphs 1 and 2 shall pay a fee determined and notified by the Minister of Ministry of Food and Drug Safety.

⑥ “Minor matters prescribed by the Ordinance of the Prime Minister” in accordance with the proviso to Article 38-2 (2) of the Act refers to matters falling under each of the following subparagraphs among matters that have been determined conformity.

1. Change of location of work place or laboratory due to reorganization of administrative district
2. Change of name of manufacturing facility due to change of company name
3. Other matters determined and notified by the Minister of Ministry of Food and Drug Safety

⑦ In addition to the matters specified in Paragraphs 1 through 6, the details necessary for the procedures and methods for determining conformity with changes shall be determined and notified by the Minister of Ministry of Food and Drug Safety.

[newly established on December 29, 2022]

Article 48-4 (Conformity Determination Verification and Investigation, etc.) ① Verification and investigation pursuant to Article 38-3 Paragraph 1 of the Act shall, in principle, be carried out by on-site inspection. However, if the Minister of Ministry of Food and Drug Safety determines that it is difficult to conduct an on-site inspection due to natural disasters or the outbreak of an infectious disease, it may be verified and investigated through a written investigation, etc.

(2) When conducting verification and investigation under Article 38-3 (1) of the Act, the head of a regional office shall notify the manufacturer of drugs, etc. of the following matters in writing no later than 7 days prior to the date of the relevant verification or investigation.

1. Scope of verification and investigation
2. Verification and investigation period.
3. Personnel for verification and investigation

③ Notwithstanding paragraph 2, if it is determined that the purpose of the verification or investigation cannot be achieved due to destruction of evidence, etc. when the head of the regional office notifies the relevant matters in advance prior to conducting the verification or investigation, A document containing the matters in each subparagraph of Paragraph 2 may be presented to the manufacturer of the relevant medicinal product, etc., or the manufacturer of the relevant medicinal product, etc. may be notified orally of the purpose of verification and investigation.

④ When ordering necessary measures, such as cancellation of conformity determination and corrective order as a result of verification and investigation pursuant to Article 38-3 Paragraph 1 of the Act, the head of the regional office shall inform the manufacturer of pharmaceuticals, etc. of the following matters in writing.

1. Measures
2. Reason for Action
3. Action Date
4. Other matters deemed necessary by the Minister of Ministry of Food and Drug Safety for the relevant measures.

⑤ In addition to the matters specified in paragraphs 1 through 4, details necessary for verification and investigation of compliance with GMP shall be determined and announced by the Minister of Ministry of Food and Drug Safety.

[newly established on December 29, 2022]

Article 48-5 (Cancellation of Conformity Determination, etc. of Pharmaceuticals, etc.) In Article 38 (3) Paragraph 3 Subparagraph 3, cases in which matters determined by the Ordinance of the Prime Minister are not observed among matters concerning GMP refer to the case falling under any of the following subparagraphs;

1. In the case of selling medicines, etc. by incorrectly preparing records on GMP for pharmaceuticals, etc. after receiving the Conformity Determination
2. In case records on GMP for pharmaceuticals, etc. are omitted after receiving determination of conformity

3. If there is a concern that the quality may be affected by not preparing detailed standards or procedures for compliance with GMP for pharmaceuticals, etc.
4. If necessary measures are not implemented as a result of product quality evaluation in accordance with the GMP for pharmaceuticals, etc.

② Standards for cancellation of conformity determination of pharmaceuticals, etc. pursuant to Article 38-3 Paragraph 3 of the Act are as in Annex 5-2.

[newly established on December 29, 2022]

Article 48-6 (Scope of Duties, etc. of GMP Inspectors of Pharmaceuticals, etc.) ① The scope of duties of a GMP inspector (hereinafter referred to as "GMP inspector") of pharmaceuticals, etc. pursuant to Article 38-4 Paragraph 3 of the Act is as follows:

1. Investigation and evaluation of compliance with GMP for pharmaceuticals, etc.
2. Review of evaluation data on GMP for pharmaceuticals, etc.

② A certificate proving the identity of a GMP inspector shall be in accordance with Form No. 82-6.

[newly established on December 29, 2022]

Article 48-7 (Training, etc. of GMP Inspectors) ① Education and training courses pursuant to Article 38-5 Paragraph 1 of the Act shall be laws, systems, and technologies necessary to investigate and evaluate compliance with GMP for pharmaceuticals, etc.

② A Minister of Ministry of Food and Drug Safety may designate any of the following organizations or institutions as education and training institutions for GMP for pharmaceuticals, etc.(hereinafter referred to as 'Education 、 Training institution " in this Article) pursuant to Article 38-5 Paragraph 2 of the Act,

1. An incorporated association organized under Article 67 of the Act
2. Korea Institute of Drug Safety & Risk Management (hereinafter referred to as "Institute of Drug Safety and Risk Management") established in accordance with Article 68-3 of the Act
3. University with drug-related departments or majors among universities under Article 2, subparagraph 1 of the Higher Education Act
4. Institutions or specialized organizations established to carry out other drug-related affairs.

③ An organization or institution that intends to be designated as an education and training institution pursuant to paragraph (2) shall meet all of the following standards for designation:
1. The course and content of education and training shall be appropriate;
2. Appropriate operating organizations, human resources, and educational facilities and equipment necessary for

conducting education and training shall be equipped;

④ A head of an organization or institution that intends to be designated as an education/training institution pursuant to Paragraph 2 shall submit an application for designation as an education/training institution in Attachment writing form 82-7 to the Minister of Ministry of Food and Drug Safety with the following documents attached.

1. Documents proving that it falls under any of the subparagraphs of Paragraph 2
2. Data on the operating organization and human resource status to conduct training
3. Data on holding status of educational facilities and equipment
4. Education Enforcement Regulations
5. Education implementation plan

(5) The public official in charge of receiving the application pursuant to paragraph (4) shall verify the certificate of corporate registration (applicable only when the applicant is a corporation) through the joint use of administrative information pursuant to Article 36 (1) of the Electronic Government Act.

⑥ A Minister of Ministry of Food and Drug Safety may conduct a on-site inspection to evaluate whether the contents of the application meets the designation criteria under Paragraph 3 when an application is received under Paragraph 4.

⑦ When an education/training institution was designated, a Minister of Ministry of Food and Drug Safety shall issue a letter of the designation in Form No. 82-8 to the applicant.

⑧ A Minister of Ministry of Food and Drug Safety shall, when entrusting education and training courses under Paragraph 1 to institutions designated as education and training institutions under Paragraph 7, announce the institution concerned.

⑨ Details necessary for the designation and management of education and training institutions other than those specified in paragraphs 1 through 8 shall be determined and notified by the Minister of Ministry of Food and Drug Safety.

[newly established on December 29, 2022]

Article 49 (Reporting on Performance of Production and exportation and Importation of Medicinal Products, etc.)

(1) A marketing authorization holder and a quasi-drug manufacturer shall report to the Minister of Ministry of Food and Drug Safety the production performance and export record of the previous year in accordance with Article 38 (2) of the Act and a medicinal product, etc. importer shall report to the Minister of Ministry of Food and Drug Safety the import performance of the previous year through corporation organized according to the Article 67 of the law such as Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) in accordance with Article 42 (5) of the Act as prescribed by the Minister of Food and Drug Safety: Provided, That for drug products (including

narcotics, psychotropic drugs and ultra-narcotics, but excluding medicinal gases), the production or import performance shall be reported on a quarterly basis to the Minister of Ministry of Food and Drug Safety and the President of the Korea Pharmaceutical Information Service ("KPIS") in accordance with Article 47-2 (1) of the Act.

(2) Notwithstanding the provision of paragraph (1), if the medicinal products, etc. importer imports medicinal products, etc. after making a standard customs prediction report in an electronic trade document pursuant to the Electronic Trade Facilitation Act, the import record may not be separately reported.

(3) If a marketing authorization holder of medicinal product discontinues production, importation and supply of drug products notified by the Minister of Health and Welfare after consultation with the Minister of Ministry of Food and Drug Safety, he/she shall report on reasons therefor no later than 60 days before the suspension day to the Minister of Ministry of Food and Drug Safety as announced by the Minister of Ministry of Food and Drug Safety: Provided. That in case where production, importation and supply has been suspended due to force majeure or sudden suspension of the supply and demand of raw materials, the reasons therefor shall be reported to the Minister of Food and Drug Safety no later than 10 days after the day of suspension.

(4) A marketing authorization holder of medicinal product, a quasi-drug manufacturer, and an importer of medicinal products, etc. who made reporting under paragraph (1) shall archive documents related to such reporting of production or importation performance for two years.

Article 49-2 (Methods of Identification Mark)

(1) Identification mark (hereinafter referred to as "identification mark") pursuant to Article 38-2 (1) of the Act shall have distinctive shape and color or printed or engraved with letters, numbers, symbols, designs, marks, logos or a combination thereof.

(2) Identification mark shall not be defaced or erased and shall not overlap with the identification marks of other medicinal products.

[This Article is newly established. Sep. 25, 2015]

Article 49-3 (Registration Procedures, etc. of Identification Mark)

(1) A person who intends to register the identification mark of medicinal products pursuant to Article 38-2 (1) of the Act shall submit the application for registration of identification mark for medicinal products (including an electronic application form) in Form No. 49-2 to the head of the organization consigned to conduct registration of identification mark (hereinafter referred as to “registration office of identification mark”) pursuant to Article 38-2 (3) of the Act along with the following documents (including the electronic document). The same shall apply when intending to change matters that have been registered:

1. Product information such as product name, active ingredient and its content and contents of

identification mark;

2. Two samples of the medicinal product;
3. Package insert for medicinal product;
4. A copy of the certificate of approval or notification of product; and
5. Details in the changes of the identification mark (applicable only for application for registration of changes).

(2) If the identification mark to be registered pursuant to Paragraph (1) contains a unique mark identifying a marketing authorization holder, a person who intends to register the unique mark as an identification mark shall submit the application for registration of identification mark for business (including an electronic application form) in Form No. 49-3 to the head of the registration office of identification mark along with the following documents (including the electronic document). The same shall apply when intending to change matters that have been registered:

1. A copy of the business license; and
2. A copy of the license for manufacturing business or the certificate of registration of importing business.

(3) If the identification mark for which an application has been submitted pursuant to Paragraph (1) or (2) is suitable for the method of identification mark, the head of the registration office of identification mark shall include the information about the identification mark in the database and issue a certificate of registration of identification mark for medicinal products in Form No. 49-4 or the certificate of registration of identification mark for businesses in Form No. 49-5.

(4) The person who intends to register the identification mark pursuant to Paragraphs (1) and (2) shall pay the fee prescribed and notified by the Minister of Ministry of Food and Drug Safety.

(5) The head of the registration office of identification mark shall report the status of registration of identification mark to the Minister of Ministry of Food and Drug Safety each quarter within one month after the quarters ends.

(6) The Minister of Ministry of Food and Drug Safety may request the head of the registration office of identification mark to submit the necessary data in order to efficiently manage the information about identification mark. In this case, the head of the registration office of identification mark in receipt of the request for submission of data shall comply with the request.

(7) In addition to the matters prescribed in Paragraphs (1) to (3), details of the subjects, standards, procedures, methods, etc. of registration of the identification mark shall be prescribed and notified by the Minister of Ministry of Food and Drug Safety.

[This Article is newly established. Sep. 25, 2015]

Article 50 (Submission of Health Hazard Evaluation and Recall Strategy)

(1) When sellers of medicinal products, etc., pharmacy founders, sellers of OTC drugs or medical institution founders who are eligible to sell or deal with medicinal products, etc. pursuant to Article 39

(1) of the act suspect that the medicinal products, etc. have a problem in the safety and efficacy pursuant to the former part of Article 39 (1) of the act (hereinafter referred to as "medicinal products, etc. subject to recall"), they shall promptly stop distributing and selling the relevant medicinal products, etc. and notify marketing authorization holders of medicinal products, manufacturers of quasi-drugs or importers of medicinal products, etc. (hereinafter referred to as a "recall obligator") thereof.

(2) The recall obligator shall evaluate the hazard of medicinal products, etc. in question immediately when medicinal products, etc. manufactured or imported by him/her are suspected as medicinal products, etc. subject to recall pursuant to each of the following criteria: <Revised on Aug. 21, 2014>

1. Class 1 hazard
   A. When causing incurable serious side effects or death by using the medicinal products, etc.;
   B. When fatal ingredients are included;
   C. When causing temporary or potential life threatening consequences due to mislabeling of medicinal products, etc.
2. Class 2 hazard
   A. When causing temporary or medically curable side effects by using the medicinal products, etc.;
   B. When the medicinal products, etc. do not conform to the quality standards announced by the Minister of Ministry of Food and Drug Safety or are not fatal such as excessive active ingredients.
3. Class 3 hazard
   A. When use of medicinal products rarely results in side effects, but efficacy is not demonstrated;
   B. When use of medicinal products rarely results in side effects, but safety or efficacy problem is observed owing to change of color, taste or packaging materials.

(3) The recall obligator shall take necessary actions such as suspension of sales regarding the medicinal products, etc. falling under the subparagraphs of paragraph (2), submit the recall strategy provided in the Form No. 50 to the Commissioner of Regional Korea Food and Drug Administration within 5 days from the date the defect of safety and efficacy is known. In cases where it is difficult to submit the recall strategy within 5 days, the reason shall be reported to the Commissioner of the Regional FDS and the extension of the time limit shall be requested. In this case, the recall obligator may submit the recall strategy through the computer program prescribed by the Minister of Ministry of Food and Drug Safety.

(4) When the recall strategy pursuant to paragraph (3) is submitted, the following documents shall be attached:

1. Copies of manufacturing or importing records of the product and records such as the amount and the date of sales etc. by retailer;
2. Recall strategy to be notified pursuant to Article 89 (3);
3. Explanatory documents with the reason for the recall.

(5) The recall obligator of medicinal products, etc. subject to recall shall establish the due date of completion of recall pursuant to the categories of each of the following subparagraphs when the recall

strategy is prepared pursuant to paragraph (3). However, when it is difficult that the recall is completed within the period of the relevant class, it may be allowed to report the reason to the Commissioner of the Regional FDS and to set exceeded time limit.

1. Class 1 hazard: within 15 days from the first day the recall is implemented;
2. Class 2 or 3 hazard: within 30 days from the first day the recall is implemented.

(6) The Commissioner of the Regional FDS may order the recall obligator of the medicinal products, etc. subject to recall to revise the recall strategy reported pursuant to paragraphs (3) and (4) when the recall strategy is considered as insufficient.

(7) When the recall strategy pursuant to paragraph (3) is reported, the Commissioner of the Regional FDS shall report the fact to the competent Mayor or Governor of the location of the recall obligator.

(8) Details concerning hazard evaluation procedure, preparation and Revised on of recall strategy etc. pursuant to paragraphs (1) through (7) shall be announced by the Minister of Ministry of Food and Drug Safety.

Article 51 (Reporting on Discontinuation of Business)

(1) When a manufacturer of medicinal products, a contract manufacturing and sales business person, or an importer intends to report discontinuation, temporary closure or reopening pursuant to subparagraphs 1 and 2 of Article 40 (1) and Article 42 (5) of the Act, he/she shall submit a report form provided in Form No. 51 (including an electronic document) for discontinuation, temporary closure or reopening of the manufacturing business, contract manufacturing and sales business, or importing business along with manufacturing business license of medicinal products, etc., contract manufacturing and sales business register, or importing business register (for discontinuation of business, include licenses and registers of all products) to the Commissioner of the Regional FDS. <Revised on Sep. 25, 2015, Dec. 13, 2017>

(2) When the manufacturing supervisor, an import manager or a safety control manager is changed pursuant to Article 40 (1) 3 of the Act and Article 42 (5) of the Act, a manufacturer, an importer or a contract manufacturing and sales business person of medicinal products, etc. shall submit a report form provided in the Form No. 52 (including an electronic document) together with documents of each of the following subparagraphs and the certificate of license or report to the Commissioner of the Regional FDS. <Revised on Sep. 25, 2015, Dec. 13, 2017>

1. for manufacturers: documents pursuant to Article 42 (5) 1 or Article 46 (3) 1 and the certificate of medicinal products manufacturing business license or quasi-drugs manufacturing business register(Cases issued in electronic form are excluded);
2. for importers: attached documents pursuant to Article 58 (1) or a document which confirms the qualification of safety control manager applied mutatis mutandis pursuant to Article 60 (1) and the importing business register(Cases issued in electronic form are excluded);
3. for contract manufacturing and sales business persons: documents pursuant to Article

46 (3) 1 and the certificate of contract manufacturing and sales business report(Cases issued in electronic form are excluded).

(3) When the position of a manager or a safety control manager is closed, a manufacturer, an importer or a contract manufacturing and sales business person of medicinal products, etc. shall submit a report form provided in the Form No. 53 (including an electronic document) together with the certificate of license or register to the Commissioner of the Regional FDS.

(4) When the Commissioner of the Regional FDS receives a report pursuant to paragraph (1) to (3), the reported matter shall be written on the relevant register and certificate of approval or certificate of report.

(5) In cases where it is possible to check the information concerning the attached documents pursuant to paragraphs (1) to (3) through common use of administrative information pursuant to Article 36 (1) of the Electronic Government Act, the check may substitute the attached documents.

(6) If a manufacturer of medicinal products, etc., or a person who has obtained an approval for sales intends to report a discontinuance or a temporary suspension of business, he/she shall take the following measures: <Newly established, Dec. 13, 2017>

1. Recall or measures necessary for the recall of medicinal products, etc. being distributed pursuant to Article 39 (1) of the Act;
2. Disposal of or measures necessary for the disposal of the relevant medicinal products, etc. pursuant to Article 71 of the Act;
3. Implementation of the order announced under Article 72 of the Act.

(7) The “documents or data prescribed by Ordinance of the Prime Minister” to be submitted by a manufacturer of medicinal products, etc., or a person who has obtained an approval for sales when filing a report of resuming business shall mean the facilities inspection results, status of retention of medicinal products, etc., plans of measures for medicinal products, etc. being retained or documents verifying completion of measures in the manufacturing site of medicinal products, etc. <Newly established, Dec. 13, 2017>

Article 52 (Product Approval of Manufacture and Sale of Pharmacy Medication and Dispensary Medication)

(1) A person who intends to prepare pharmacy medications pursuant to the body of Article 41 (1) of the Act shall fill out and submit a report form of the Form No. 54 (including an electronic document) and a person who intends to prepare medications in a dispensary of a medical institution (hereinafter referred to as "dispensary medication") shall fill out and submit a report form of the Form No. 55 (including an electronic document) to heads of Si/Gun/Gus: Provided, That a person who intends to prepare dispensary medications pursuant to the proviso to Article 41 (1) of the Act shall submit the report form to Special Metropolitan City Mayor, Metropolitan City Mayor, Provincial Governor or Special Self-governing Governor. The same shall apply to the cases of the discontinuance of preparation of

pharmacy medications and dispensary medications.

(2) Mayors, provincial governors or heads of Si/Gun/Gus may request samples of products to be submitted upon receipt of product report of pharmacy medications and dispensary medications.

Article 53 (Manufactured Product Report Registers of Pharmacy Medication or Dispensary Medication)

When Mayors, provincial governors or heads of Si/Gun/Gus accept a report pursuant to Article 52, the following matters falling under the following subparagraphs shall be entered in the manufactured product report register and a report certificate of the Form No. 56 for pharmacy medication or No. 57 for dispensary medication shall be issued.

1. Product to be manufactured;
2. Report number and the date of report;
3. Name of medication manufacturer and resident registration number;
4. Name of the pharmacy which manufactures medication and its location (name of the medical institution and its location for dispensary medication);
5. Name, license number and resident registration number of a pharmacist or an oriental pharmacist who manages the dispensary of a medical institution for dispensary medication;
6. Name and license number of prescribing doctor (only for the dispensary medication which is prepared according to the doctor's prescription).

Article 54 (Scope of Pharmacy Medication and Dispensary Medication)

The scope of Pharmacy Preparation and Pharmacy Medication pursuant to Article 41 (3) of the Act shall be as the following subparagraphs;

1. Medicinal products listed on the Pharmacopoeia of Republic of Korea which do not fall under the any of the following subparagraphs and are announced by the Minister of Ministry of Food and Drug Safety;
   A. pharmacy medications;
      1) Medications which include narcotics or psychotropic drugs;
      2) Antibiotics, biological products and sex hormone preparations;
      3) Medications which are manufactured in Korea or imported from foreign countries;
      4) Injections, tablets, pills;
      5) Products falling under prescription drugs.
   B. Dispensary medications;
      1) Medications falling under Item A 1) through 3);
      2) Medications falling under non-prescription drugs.
2. Medications which are not listed in the Pharmacopoeia of Republic of Korea and are announced by the Minister of Ministry of Food and Drug Safety.

Article 55 (Facilities Standards of Manufacturing Site of Pharmacy Medications and Dispensary Medications)

(1) A person who intends to prepare pharmacy preparation at pharmacies pursuant to Article 41 (3) of the Act shall have apparatus necessary for preparing pharmacy preparation.

(2) There shall be a working area and a laboratory in pharmacy medication premises pursuant to Article 41 (3) of the Act.

(3) With respect to the standard other than the standard referred to in paragraph (2), Article 3 of the Enforcement Decree on the Standards of Facilities of Manufacturers and Importers of Medicinal Products, etc. and Articles 2 through 5 of the Enforcement Regulation of the Enforcement Decree on the Standards of Facilities of Manufacturers and Importers of Medicinal Products, etc. shall apply mutatis mutandis.

Article 56 (Manufacture and Control of Pharmacy Medication or Dispensary Medication)

Pursuant to Article 41 (2) of the Act, a person who intends to prepare pharmacy medications or dispensary medications shall comply with the following requirements. <Revised on Aug. 21, 2014>

1. The person shall conduct strict production and quality controls, prepare production and quality control records and maintain them for 2 years from the date of manufacture.
2. The person shall conduct strict control and supervision of personnel engaged in production and quality controls.
3. The person shall comply with requirements for production and quality controls as notified by the Minister of Ministry of Food and Drug Safety.

Article 56-2 (Notification for Importing Business of Medicinal Products, etc.)

(1) A person who intends to report the importing business of medicinal products pursuant to Article 42 (1) of the Act shall submit the notification application on importing business of medicinal products in Form No. 7-2 to the Commissioner of the Regional Office of the Food and Drug Safety along with the following documents (including electronic documents):

1. Medical certificate issued by a specialist which proves that he/she does not fall under the main text of Subparagraph 1 of Article 5 of the Act or the proviso of the same subparagraph and a medical certificate issues by a doctor which proves that he/she does not fall under subparagraph 3 of the same Article; and
2. A document which confirms the qualification of the import manager and safety control manager pursuant to Articles 36 and 37-3 of the Act which are applied mutatis and mutandis pursuant to Article 52 (5) of the Act, or a letter of approval by an import manager in Form No. 44.

(2) The Commissioner of the Regional FDS in receipt of the notification pursuant to Paragraph (1) shall confirm the following documents through joint use of administrative information pursuant to Article

36 (1) of the Electronic Government Act. However, in case of Subparagraph 2, if a person making the report does not agree with the confirmation, he/she shall be instructed to attach a copy:

1. Certificate of corporation registration (applicable only to corporations);
2. Pharmacist's license (only applicable if the import manager or safety control manager is a pharmacist)

(3) A person who intends to report the importing business of medicinal products, etc. pursuant to Paragraph (1) shall apply for the approval of imported products or make a report of imported products for one or more products belonging to that industry at the same time.

(4) A person who intends to report the importing business of medicinal products, etc. pursuant to Paragraph (1) shall pay a fee determined and notified by the Minister of Ministry of Food and Drug Safety.

[This Article is newly established. Sep. 25, 2015]

Article 57 (Omission of Procedures for Notification of Importing Business of Medicinal Products and Approval and Notification of Imported Medicinal Products, etc.)

(1) Pursuant to Article 42 (2) 2 of the Act, medicinal products, etc. excluded from those subject to marketing approval or notification of importation shall be as the following subparagraphs: Provided, That the same shall not apply to the products required to submit documents thereof pursuant to Article 4 (1) 1 among medicinal products, etc. falling under the subparagraphs 4 to 5. <Revised on Aug. 21, 2014, Sep. 25, 2015, March 30, 2018>

1. Products which are directly imported by the Chairperson of Korea Orphan and Essential Drug Center pursuant to Article 91 of the Act to carry out supply business of orphan drugs and medicinal products for treating rare diseases and products of which urgent introduction is recognized as necessary to treat patients.;

1-2. Products deemed necessary to be introduced urgently for the treatment of patients by the Minister of Ministry of Food and Drug Safety at the request of the head of the relevant central administrative agency or related institutions and organizations

2. Investigational products, etc. of which clinical trial plan is approved pursuant to Article 24 (1);
3. Drug substances and comparator (including placebo) to be used for clinical trial purposes;
4. Drug substances which are directly imported by a manufacturer of medicinal products, etc. pursuant to Annex 1, 1-M (including drug substances and herbal medicine to be designated as standardized products pursuant to the subparagraph 5 of Article 62) to be used as ingredients of medicinal products, etc. which are manufactured by the manufacturer himself/herself;
5. Herbal medicines other than those designated as standardized products pursuant to the subparagraph 5 of Article 62;
6. Medicinal products, etc. such as medicinal products, etc. for self-treatment or aid announced by the Minister of Ministry of Food and Drug Safety.

(2) A person who intends to import only medicinal products, etc. falling under subparagraphs 1 to 4 or subparagraph 6 of paragraph (1) of this Article shall be excluded from being subject to notification of the importing business pursuant to Article 42 (6) of the Act.
<Newly established, Sep. 25, 2015>
[Revised on of the title, Sep. 25, 2015]

Article 58 (Reporting of Import Manager, etc.)

(1)Importers shall have one or more pharmacists or oriental pharmacists as an import manager who manages importing affairs pursuant to Article 42 (4) of the Act and submit the report form provided in Form No. 45 (including an electronic document) together with a document which confirms the qualification of the import manager or a certificate of approval of import manager in Form No. 44(case issued in electronic form is excluded) and the certificate of register of importing business of medicinal products to the Commissioner of the Regional Office of Food and Drug Safety. In such cases, the proviso of Article 36 (1) of the Act, or Article 36 (2) of the Act or Article 42 of this Regulation shall apply mutatis mutandis to the qualification of import manager of biological products or quasi-drugs (limited to the case of products falling under subparagraph 7 A of Article 2 of the Act). <Revised on Sep. 25, 2015, Sep 7, 2020, Mar 8, 2021>

(2) Importers of medicinal products shall have one or more safety control manager pursuant to Article 42 (5) of the Act in addition to import manager referred to in paragraph (1) and submit a report form provided in Form No. 49 (including an electronic document) together with a document which confirms the qualification of the safety manager and the certificate of register of importing business of medicinal products to the Commissioner of the Regional FDS: Provided, That importers of herbal substances, raw materials, medicinal gases, or products that are not directly applied to human body may not have such safety control manager. <Revised on May 9, 2014, Sep. 25, 2015, June 30, 2016>

(3) In such instance, on receipt of the report under paragraphs (1) and (2), the Commissioner of the Regional FDS shall verify the license of pharmacist (limiting to cases where the import manager or safety manager is a pharmacist) through the procedure for common use of administrative information in accordance with Article 36 (1) of the Electronic Government Act and, if the applicant does not consent to such verification, copies thereof should be attached.

(4) When there are two or more import managers or safety control managers pursuant to paragraphs (1) and (2), their roles and responsibilities shall be clearly defined.

(5) Notwithstanding paragraphs (1) and (2), each of the following subparagraphs shall apply to cases where a manufacturer of medicinal products, etc. or a drug wholesaler also engages in importing affairs.

1. a manufacturer of medicinal products may choose not to have an import manager and safety control manager separately;
2. a manufacturer of quasi-drugs or a drug wholesaler may choose not to have an import manager.
3.

Article 59 (Import Register of Marketing Approval and Certificate of Approval, etc.)

When marketing approval or notification of importation of medicinal products, etc. is granted or accepted pursuant to Article 4 or Article 5, the Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS shall put each of the following matters on the register and, when approving the matters concerned, he/she shall issue a certificate of approval provided in the Form No. 10 for marketing approval of importation of medicinal products, etc. or a certificate of completion of notification provided in the Form No. 13 of notification of importation of medicinal products, etc. respectively.

1. for marketing approval of importation
    A. Approval number and date of approval; and
    B. Name of product.
2. for product report of importation
    A. Report acceptance number and date of acceptance; and
    B. Name of product.

Article 60 (Duties of Compliance, etc. for Importers, etc.)

(1) The import manager shall comply with the following pursuant to Article 42 (5) and (6) of the Act:

1. Hygienically manage the warehouse and facilities of the laboratory so that there is no harm to public health and to prevent intrusion of insects, etc., cross contamination or pollution, etc. from the outside.
2. Thoroughly check the employees' health and hygiene status and focus on education and supervision for the import and sales of medicinal products with an excellent quality.
3. Accurately import according to the manufacturing formulae, quality control standard documents, etc.
4. Warehouses and laboratories shall not contain anything that may cause harm and shall not leak or release substances that are harmful to the public health.
5. Tests, inspections or examinations necessary from the time of receipt to the delivery of medicinal products and materials, etc. shall be performed thoroughly. However, for drug substances of which the importation was performed by proxy at the request of the manufacturers of orphan drugs or drug products, the test, inspection or the examination report of relevant orphan drugs or drug substances conducted in the country of origin or by the original manufacturer can replace the importer's test, inspection, or examinations.
    A. Orphan drug
    B. Drug substances imported as a proxy at the request of the finished drug manufacturer
    C. Drugs recognized by the Minister of Ministry of Food and Drug Safety that there is a risk of disruption to patient treatment if supply is discontinued because there is no substitute drug in Korea among essential national medicines
6. Prepare import records and quality control records for each batch and keep them for at least 3 years from the date of customs clearance.

(2) The importer shall comply with the following and each subparagraph of Paragraph (1) pursuant to Article 42 (5) and (6) of the Act:

1. Thoroughly inspect the quality of medicinal products, etc., and sell only those products that have passed the inspection.
2. If new data are obtained or information, etc. has become known in regards to the safety/efficacy of approved or reported products (including cases of side effects caused by the use of medicinal products, etc.) and when an investigation is conducted to collect, analyze and evaluate information on safety/efficacy, report shall be made and appropriate measures shall be taken pursuant to the provisions of Subparagraphs 6 to 8 of the post-marketing safety control standards for medicinal products, etc. in Annex 4-3.
3. If a measuring cup, a measuring spoon, etc. that are not medical devices pursuant to the Medical Devices Act are used for pediatric medicinal products prescribed by the Minister of Ministry of Food and Drug Safety (hereinafter referred to as "pediatric medicinal products"), a measuring cup, a measuring spoon, etc. that meets the criteria prescribed by the Minister of Ministry of Food and Drug Safety shall be used.
4. Do not use medicinal products that have been found to infringe other people’s patent rights.
5. Do not store medicinal products, etc. in a place other than a warehouse pursuant to Article 42 (3) of the Act and Article 6 (1) 1 of the Decree on Facility Standards for manufacturing Business and Importers of Drugs, Etc.
6. Import medicinal products that are manufactured in conformity with the standards of the relevant country which is equivalent to the GMP standards Annex 1, Annex 1-2, Annex 2, Annex 3, Annex 3-2, or Annex 3-3 or 3-4, and when importing medicinal products, follow the import control standards for medicinal products, etc. in Annex 6-2.
7. Import quasi-drugs that are manufactured in conformity with the standards of the relevant country which is equivalent to the GMP standards Annex 1 pursuant to Subparagraph 9-2 of Article 48, and when importing quasi-drugs, follow the import control standards for medicinal products, etc. in Annex 6-2.
8. Importers of plasma derivatives shall comply with control standards for plasma in Annex 6-2.
9. In case of importing medicinal products, etc. that have used drug substances subject to registration, only import medicinal products that are manufactured by using any of the following items:
    A. Drug substances announced by the Minister of Ministry of Food and Drug Safety on the internet, etc. pursuant to the latter part except each subparagraph of Article 16;
    B. Drug substances of which the data under the main text except each item of Article 4 (1) 7 or the data under each item of Article 4 (1) 7 are submitted pursuant to Article 5 (2) 6 when the importer of medicinal products, etc. obtains permission for or notifies imported products him/herself pursuant to Article 4 (1) or Article 5 (2) of the Act.

10. In regards to the submission and investigation of data, GMP, items to be labeled, etc. that are required for safety and efficacy of medicinal products, etc., follow the instructions given by the Minister of Ministry of Food and Drug Safety.
11. For medicinal products prescribed by the Minister of Ministry of Food and Drug Safety, import and supply products of a small packing unit, such as PTP, as prescribed by the Minister of Ministry of Food and Drug Safety. In this case, for non-prescription pharmaceuticals, the small packing unit shall be at least 10 tablets (or capsule, etc.) except in situations that require packages that is less than the small packing unit due to its nature.
12. Supply first-aid medicines in one-day packs. However, if the Minister of Health and Welfare determines otherwise, taking into consideration the daily dose, the number of doses per day, the dosage form, and the descriptions on the outer package, they shall be supplied accordingly.
13. Importers of cigarette-type smoking cessation aids supplements in quasi-drugs shall import cigarette-type smoking cessation aids conforming to the acceptance criteria, acceptance error tolerance and measurement standards of tar, nicotine and carbon monoxide prescribed by the Minister of Ministry of Food and Drug Safety. And for products being sold in the market, he/she shall request the measuring institution specified by the Minister of Strategy and Finance to measure tar, nicotine, and carbon monoxide each quarter within one month after the start of a quarter pursuant to Article 25-2 of the Tobacco Business Act and keep the results for more than 3 years from the date of measurement.
14. For the herb medicines prescribed and notified by the Minister of Ministry of Food and Drug Safety among herb medicines designated as those subject to standardized products pursuant to Subparagraph 5 of Article 62, comply with the matters prescribed and notified by the Minister of Ministry of Food and Drug Safety in regards to their characteristics, condition, quality, storage methods, etc.
15. Do not sell medicinal products of which the expiration dates of approval or notification of imported products have passed.
16. Implement a risk management plan for the safe use of medicinal products (only for medicinal products for which a risk management plan is submitted).
17. Collect and evaluate safety information about medicinal products pursuant to the post-marketing safety control standards for medicinal products, etc. in Annex 4-3 and perform post-marketing safety control work such as establishment, etc. of appropriate safety measures.
18. Comply with regulations on import and export of medicinal products, etc. prescribed by the Foreign Trade Act, and perform the standardized customs clearance and report with an electronic trade document pursuant to the Electronic Trade Facilitation Act.

(3) Article 43 (2) shall apply mutatis mutandis to the notification of the import manager’s non-participation in management work; Article 44 and 45 to the training of import managers. In this case, "manufacturing supervisor" shall be regarded as "import manager”; “manufacturing site” as “business

office"; and "manufacturing" as "import."

(4) Article 46 shall apply mutatis mutandis to safety control managers, etc.; Article 47 to the matters, etc. to be complied by safety control managers; Article 47-2 to the contents, time, method, etc. of the safety control managers training; and Article 47-3 to the designation, cancellation of designation, etc. of training institutions for safety control managers. In this case, "marketing authorization holder" shall be regarded as "importer," "manufacturing business license or register of contract manufacturing and sale business" as "register of importing business" and "manufacturing and sales" as "importation."

[Revised on of the Entire Article, Dec. 13, 2017]

Article 60-2 (Registration of foreign manufacturers) (1) Pharmaceuticals prescribed by Ordinance of the Prime Minister in Article 42(7) means that pharmaceuticals which has received or reported approval by item according to Article 42(1).

1. Medicines, etc. falling under Article 42 (7) 1 and 3 of the Act
2. Drug substances that are used as or contain active ingredients of pharmaceuticals among drug substances under Article 42 (7) 2 of the Act
3. As the main ingredient of quasi-drugs (solid dosage forms for internal use, liquid formulations for internal use, and only ointments for external skin and cataplasma drugs that meet the standard manufacturing criteria for drugs notified by the Minister of Ministry of Food and Drug Safety) among drug substances pursuant to Article 42 (7) 2 of the Act Drug substances used as active substances or containing active substances.

(2) An importer who intends to register the following matters on foreign manufacturers(refers to foreign-based facility which manufactures and performs quality control. Hereinafter the same shall apply.) shall submit registration application of foreign manufacturer of paragraph 57(2) of annexed form(electronic application is included) attached with summary data on human resources・facility・manufacturing・quality control(electronic document is included, imported product is only applied in accordance with Article 48(9) and paragraph 9(2)) to the Minister of Ministry of Food and Drug Safety.

1. The name of foreign manufacturer, matters concerning place of location and manager
2. Matters concerning product name of imported product, type, dosage form, approval number or register acceptance number

(3) An importer who intends to change the following matters concerning registration for foreign manufacturer in accordance with Article 42 (8) shall submit registration change application of foreign manufacturer of paragraph 57(2) of annexed form (electronic application is included) to the Minister of Ministry of Food and Drug Safety. In this case, the importer shall attach each document verifying changed matters(electronic document is included).

1. The name and location of foreign manufacturer(included administrative district change)
2. The product name, type, dosage form, authorization number or number of acceptance report.

(4) An importer shall pay commission notified by the Minister of Ministry of Food and Drug Safety, if he/she intends to apply for registration or change registration of foreign manufacturer according to paragraph (2) and (3) of the Act.

(5) In addition to the matters prescribed by the paragraphs (2) to (4), details required for registration and change registration or change notification of foreign manufacturer shall be prepared and notified by the Minister of Ministry of Food and Drug Safety.

(Newly established 6 Dec 2019)

Article 61 (Permission of Exportation or Importation of Endangered Species of Wild Fauna and Flora)

(1) Any person who desires to export, import, or carry into Korea by sea, medicinal products made from processed goods of animals and plants (hereinafter referred to as "wild fauna and flora") shall submit an approval application of Form No. 58 (including an electronic document) to export, import or carry in endangered species of wild fauna or flora, together with one document of the following subparagraphs (including an electronic document) on every business and the Ministry of Food and Drug Safety shall review the application and, when granting the approval of exportation, importation or introduction, shall issue an approval certificate of exportation, importation or introduction of Form No. 59.

1. For export;
   A. When re-exporting processed products of wild fauna and flora of foreign origin, the copy of the export certificate issued by the country that exported the processed products of wild fauna and flora, in accordance with the Convention on International Trade in Endangered Species of Wild Fauna and Flora;
   B. When exporting processed products of wild fauna and flora of Korean origin, the written explanation on the details of acquisition of the wild fauna and flora and supporting documents thereof.
2. For import;
   A. The copy of the export certificate issued by the country that exported the processed products of wild fauna and flora, in accordance with the Convention on International Trade in Endangered Species of Wild Fauna and Flora;
   B. The copy of offer sheet or import contract.
3. For introduction;
   The written explanation on the details of acquisition of the wild fauna and flora and supporting documents thereof.

(2) A person who applies for approval of exportation, importation or introduction of wild fauna and flora pursuant to paragraph (1) shall pay a fee as notified by the Minister of Ministry of Food and Drug Safety.

Article 62 (Matters to Be Observed Regarding Distribution Management Related to Safety and Quality of Medicinal Products, Etc.)

A marketing authorization holder of medicinal products, an importer of medicinal products, a wholesaler of medicinal products, a pharmacy founder, seller of medicine and medical supplies, herbal medicine shops, a wholesaler of herbal products pursuant to Article 5 of the supplementary provisions of the entire amendment of the Pharmaceutical Affairs Act, Act No.8365 pursuant to Article 47 (1) 4Aof the Act and others who are entitled to sell medicinal products pursuant to the Act shall comply with each of the following subparagraphs for distribution management related to safety and quality of medicinal products, etc. <Revised on Aug. 21, 2014, June 30, 2016>

1. Deleted <Sep. 25, 2015>
2. Medicinal products which are deteriorated, degenerated, contaminated, damaged, or have passed the expiry date or use-by date shall not be sold, stored or displayed for sale and containers and packages thereof shall not be damaged or falsified.
3. Medicinal products which are ordered to be collected or scrapped by the Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS shall not be sold, stored or displayed for sale.
4. A pharmacy founder, over-the-counter drugs seller and herbal druggist, drugs seller, druggists and wholesalers pursuant to Article 5 of Addenda to Act No. 8365 Wholly Amended Pharmaceutical Affairs Act, and a person who manages a pharmacy pursuant to Article 21 of the Act shall prepare records on disposal of adulterated medicinal products and archive them for one year.
5. A pharmacy founder, herbal druggist or drug wholesaler shall sell herbal medicines that are listed in the Korean Pharmacopoeia or the Korean Herbal Pharmacopoeia and that comply with quality control standards prescribed in Item 8 (hereinafter referred to as "standard products") and shall not sell or store and display for the purpose of sale any non-standard products for herbal medicines as notified by the Minister of Ministry of Food and Drug Safety.
6. A pharmacy founder, herbal druggist or drug wholesaler shall indicate the origin of herbal substances, if applicable.
7. The requirements in Annex 6 Good Distribution Practice for Medicinal Products for Human Use established by the Minister of Ministry of Food and Drug Safety in consultation with the Minister of Health and Welfare shall be followed.
8. Requirements for quality control of herbal substances prescribed by the Minister of Ministry of Food and Drug Safety shall be followed.

Article 62-2 (Medicines Prohibited from Acquisition through Illegal Distribution) In Article 47-4 Subparagraph 3 of the Act, “drugs prescribed by the Ordinance of the Prime Minister” refers to medicines containing etomidate.

[newly established on July 21, 2022]

[Former Article 62-2 moved to Article 62-3 <July 21, 2022>]

Article 62-3 (Registration, etc. of Patent Rights for Medicinal Products)

(1) A person who intends to apply for the registration of a patent for a medicinal product on the list of patents pursuant to Article 50-2 (1) of the Act shall submit the application for patent registration for medicinal products in Form No. 59-2 to the Minister of Ministry of Food and Drug Safety along with documents listed in each subparagraph of Paragraph (2). In this case, if documents under each subparagraph of Paragraph (2) can be verified through the common use of administrative information pursuant to Article 36 (1) of the Electronic Government, submission of documents can be replaced with such verification. <Revised on March 30, 2018.>

(2) The "documents prescribed by the Ordinance of the Prime Minister" referred to in the part other than each subparagraph of Article 50-2 (2) of the Act shall mean the documents (including electronic documents) in each of the following subparagraphs:

1. A copy of the patent register;
2. A copy of patent publication for announcement of registration;
3. Consent of patentee or exclusive licensee (hereinafter referred to as "patentee, etc.") under the Patent Act;
4. If the patentee, etc. elects a proxy, the proxy statement.

(3) The "matters prescribed by the Ordinance of the Prime Minister" referred to in Article 52-2 (2) 7 of the Act shall mean detailed descriptions of the matters in Article 50-2 (4) 2 of the Act.

(4) A person who intends to make changes to the application for patent registration pursuant to Article 50-2 (3) of the Act shall submit the application for modification of the application for registration in the patent list for medicinal products in Form No. 59-2 to the Minister of Ministry of Food and Drug Safety along with documents that can verify the changes (including electronic documents).

(5) The matters prescribed by the “Ordinance of the Prime Minister” referred to in parts other than every subparagraph of Article 50-2 (4) of the Act shall mean the following:

1. Name of the medicinal product;
2. Information about a person who has registered the patent right for medicinal products in the patent list (hereinafter referred to as "registered patentee");
3. Personal information of the patentee, etc.;
4. Personal information of the proxy;
5. Patent number;
6. Date of registration of the patent right and the expiration date;
7. Matters to be protected with a patent (hereinafter referred to as "patent claim")

(6) A person who intends to apply for registration of patent rights for medicinal products in the patent list or make changes to the application for patent registration (applicable only adding a patent claim(s)) pursuant to Paragraph (1) or (4) shall pay the fee prescribed and notified by the Minister of Ministry of Food and Drug Safety.

[This Article is newly established. March 13, 2015]

Article 62-4 (Change of Registered Matters, etc.)

(1) A person who intends apply for changes or deletion of matters listed in the patent list pursuant to Article 50-3 (1) of the Act shall submit an application for changes of the maters listed in the patent list of medicinal products in Form No. 59-4 (including an electronic application form) along with the documents that can prove the changes (including electronic documents) to the Minister of Ministry of Food and Drug Safety.

(2) A person who intends to apply for an additional period of changes pursuant to Article 50-3 (2) of the Act shall submit documents stating the purpose and reason to the Minister of Ministry of Food and Drug Safety.

(3) A person who intends to apply for a change in the matters listed in the patent list shall pay the fee prescribed and notified by the Minister of Ministry of Food and Drug Safety.

(4) A person who intends to apply for a change of matters listed in the patent list during the period of changes that has been granted additionally pursuant to Paragraph (2) shall pay a fee determined and notified by the Minister of Ministry of Food and Drug Safety.

[This Article is newly established. March 13, 2015]

Article 62-5 (Notification of the Fact about Application for Approval of Products, etc.)

(1) A person who has applied for approval of medicinal products pursuant to Article 31 (2) or (3) of the Act or applied for approval of changes related to the efficacy and effectiveness pursuant to Paragraph 9 of the Act based on data on the safety and efficacy of listed medicinal products pursuant to Article 50-4 shall give the registered patentee and the patentee, etc. of a listed medicinal product (hereinafter referred to as the "patentee, etc. of a listed medicinal product") the notice of the application for approval of products in Form No. 59-5 stating the following items:

1. Date of application for approval of products or changes;
2. The fact that an application for approval of products or changes are filed based on the safety/efficacy data of a listed medicinal product for the purpose of commercially manufacturing, importing and selling medicinal products before the expiration date of a patent listed in the patent list (hereinafter referred to as "registered patent");
3. The basis of judgment that the registered patent is invalid or that the medicinal product for which application has been filed for approval of products or changes does not infringed the registered patent.

(2) The "matters prescribed by the Ordinance of the Prime Minister" referred to in the latter part of Article 50-4 (5) of the Act shall mean the following:

1. Date of application for approval;
2. Active ingredient and its content;
3. Dosage form;
4. Dosage and administration;

5. Efficacy and effectiveness.
6. Name of the registered drug

[This Article is newly established. March 13, 2015]

Article 62-6 (Application for Prohibition of Sales)

(1) A person who intends to apply for the prohibition of sales pursuant to Article 50-5 (1) shall submit the application for prohibition of sales in Form 59-6 (including electronic application forms) along with a statement pursuant to Article 50-5 (1) of the Act and documents that can verify the following items to the Minister of Ministry of Food and Drug Safety.

1. Date of notification under Article 50-4 of the Act;
2. The fact about filing a suit or petitioning for trial under each subparagraph of Article 50-5 (2) of the Act;
3. If there is a ruling or trial ruling on lawsuits or trials under each subparagraph of Article 50-5 (2) of the Act

(2) A person who intends to apply for the prohibition of sales pursuant to Paragraph (1) shall pay a fee determined and notified by the Minister of Ministry of Food and Drug Safety.

[This Article is newly established. March 13, 2015]

Article 62-7 (Prohibition of Sales, etc.)

(1) If medicinal products that are prohibited from sales meet the requirement for prohibition of sales pursuant to Article 50-5 (1) of the Act, the Minister of Ministry of Food and Drug Safety shall inform the patentee, etc. of a listed drug and a person who has applied for approval of products or the changes thereof for medicinal products to be notified of the names of the prohibited medicinal products and the period of prohibition of sales

(2) If the reason under Subparagraphs 1 to 6, 9 or 10 of Article 50-6 (3) of the Act exist, the patentee, etc. of a listed drug and a person who has applied for approval of products or the changes thereof for medicinal products that are prohibited from sales shall inform the Minister of Ministry of Food and Drug Safety without delay.

(3) If the reason under each subparagraph of Article 50-6 (3) of the Act exist, the Minister of Ministry of Food and Drug Safety shall notify the patentee, etc. of a listed drug and a person who has applied for approval of products or the changes thereof for medicinal products that are prohibited from sales that the effect of prohibition of sales shall terminate.

[This Article is newly established. March 13, 2015]

Article 62-8 (Application for Approval for Exclusive Marketing of Products)

(1) A person who intends to apply for approval for exclusive marketing of products pursuant to Article 50-7 (1) of the Act shall submit the application form for approval for exclusive marketing of products

(including electronic application forms) in Form No. 59-7 to the Minister of Ministry of Food and Drug Safety.

(2) The "matters prescribed by the Ordinance of the Prime Minister" referred to in the preceding paragraph of Article 50-7 (3) of the Act shall mean the following:

1. Patent number;
2. Patent trial number;
3. Filing date of a petition for trial.

(3) The "documents prescribed by the Ordinance of the Prime Minister" referred to in parts other than every subparagraph of Article 50-7 (4) of the Act shall mean the following documents (including electronic documents):

1. Petition for a trial under each subparagraph of Article 50-7 (2) of the Act stating the purpose and the reason for the claim;
2. In case of disagreeing with the judgment result of each subparagraph of Article 50-7 (2) of the Act, the purpose and the reason for the claim;
3. In case of receiving a trial ruling or ruling pursuant to Article 50-8 (1) 2 of the Act, documents that can prove this;
4. If the medicinal product for which an application for approval of products have been filed requires proof of the equivalence of medicinal products, results of the test verifying the equivalence;
5. If the medicinal product for which an application for approval of products have been filed is a medicinal product requiring submission of data about clinical trial results pursuant to subparagraph 6 of Article 9, clinical trial results.

(4) The "matters prescribed by the Ordinance of the Prime Minister" pursuant to Article 50-7 (4) 5 of the Act shall mean the following:

1. Information about medicinal product for which an application for exclusive marketing has been filed;
2. Information about registered medicinal products.

(5) A person who intends to apply for approval for exclusive marketing of products pursuant to Paragraph (1) shall pay a fee determined and notified by the Minister of the Food and Drug Safety.

[This Article is newly established. March 13, 2015]

Article 62-9 (Approval for Exclusive Marketing of Products)

(1) If the medicinal product for which an application for exclusive marketing has been filed pursuant to Article 50-8 (1) of the Act satisfies the requirement for approval for exclusive marketing of the product, the Minister of Ministry Food and Drug Safety shall notify a person who has applied for exclusive marketing of the product the name of the medicinal products approved for exclusive marketing and the period of prohibition of sales pursuant to Article 50-9 (1) of the Act. <Revised on Dec. 13, 2017>

(2) The "matters prescribed by the Ordinance of the Prime Minister" pursuant to Article 50-8 (2) of the Act

shall mean the following: <Revised on Dec. 13, 2017>

1. Main ingredients and their content;
2. Dosage form;
3. Dosage and administration;
4. Efficacy and effectiveness;
5. Date of approval for exclusive marketing of products.

[This Article is newly established. March 13, 2015]

Article 62-10 (Prohibition of Sales, etc. for the Same Medicinal Products, etc.)

(1) The Minster of Ministry of Food and Drug Safety shall notify a person who has applied for approval or approval of changes of medicinal products for which exclusive marketing has been approved or the same medicinal products the period of sales prohibition pursuant to Article 50-9 (1) of the Act.

(2) The date on which marketing becomes feasible pursuant to Article 50-9 (2) and 50-10 (2) 2 of the Act shall be the later of the following dates:

1. Date of granting of approval for exclusive marketing;
2. The day after the day on which the period of a registered patent expires pursuant to Article 50-4 (1) 2.

(3) If a person who has been granted approval for exclusive marketing of the product has applied for the health care benefit pursuant to Article 41 (1) 2 of the National Health Insurance Act, he/she shall inform the Minster of Ministry of Food and Drug Safety without delay.

[This Article is newly established. March 13, 2015]

Article 62-11 (Cessation of the Effect of Prohibition of Sales of the Same Medicinal Products, etc.)

(1) A person who receives the approval of exclusive marketing product shall notify the Minster of Ministry of Food and Drug Safety without delay if there is any ground of Article 50-10 (1) 2 or (2) of the Act.

(2) If the effect of the prohibition of sales has become extinct pursuant to Article 50-10 (1) of the Act, or it has been terminated pursuant to Subparagraph (2) of the Act, the Minster of Ministry of Food and Drug Safety shall notify the person who has been granted approval for exclusive marketing of the product and the person who has been consequently granted marketing approval or approval of changes to the medicinal products whose sales have been prohibited of the fact that the prohibition of sale has ceased to exist and the date for its cessation.

[This Article is newly established. March 13, 2015]

Article 62-12 (Impact Assessment)

(1) The Minister of Ministry of Food and Drug Safety shall conduct an impact assessment (hereinafter referred to as the "impact assessment") pursuant to Article 50-11 of the Act every year.

(2) In addition to the matters prescribed in the paragraph (1), detailed requirements for implementation of

the impact assessment shall be determined by the Minister of Ministry of Food and Drug Safety.

[This Article is newly established. March 13, 2015]

Article 62-13 (Scope of the Specific Group)

The scope of the “group prescribed by the Ordinance of the Prime Minister” shall mean a group consisting of persons who fall under any of the following subparagraphs:

1. Persons who are 65 years of age or older;
2. Persons who are younger than 19 years of age;
3. Pregnant women;
4. Patients such as patients with renal impairment, etc. who are acknowledged by the Minister of Food and Drug Administration that there is a need to check adverse reactions to medicinal products.

[This Article is newly established. June 30, 2016]

Article 63 (Scope of Drugs under National Lot Release)

Medicinal products which shall be approved for national lot release pursuant to Article 53 (1) of the Act shall be prescribed by the Minister of Ministry of Food and Drug Safety such as vaccines, antitoxins, plasma derivatives and those required to be controlled at the national level among biological products (hereinafter referred to as "drugs under national lot release"): Provided, That the same shall not apply to export-only products requested by importer and the products excluded from those under national batch release by the Minister of Ministry of Food and Drug Safety.

Article 64 (Application for National Lot Release of Medicinal Products)

(1) A person who desires to obtain approval of national lot release of medicinal products pursuant to Article 53 (2) of the Act shall submit an application provided in the Form No. 60 (including an electronic document) together with data concerning manufacturing and quality control (including electronic documents) as announced by the Minister of Ministry of Food and Drug Safety, to the Minister of Ministry of Food and Drug Safety for every medicinal product of the same batch number.

(2) A person who applies for approval of national lot release of medicinal products, etc. pursuant to paragraph (1) shall pay a fee as announced by the Minister of Food and Drug Safety.

Article 65 (Sampling, etc.)

(1) When the Minister of Ministry of Food and Drug Safety receives application of national lot release pursuant to Article 64, public officials belonging to the Ministry of Food and Drug Safety or pharmaceutical inspectors of Article 78 (1) of the Act designated by the Minister of Food and Drug Safety shall take samples necessary for the national lot release from medicinal products to be approved for the national lot release, seal all the medicinal products applied for the national batch release, seal samples taken in proper containers and write the name of manufacturing site, the name of

product, the batch number, the manufacturing date, the amount of sample on the container. For imported products, the name of manufacturer and the name of importer shall also be written.

(2) Notwithstanding Paragraph 1, the Minister of Ministry of Food and Drug Safety may ask the applicant for release approval of the medicinal product to collect and submit the samples necessary for release approval, in case that the medicine shall urgently supply to properly respond to public health crises under Article 2, Subparagraph 2 of the 「Special Act on the Promotion of Development and Emergency Supply of Medical Products in Response to Public Health Emergency」. In this case, the sealing according to paragraph 1 and the container mark of the collected sample may not be indicated. <Newly established 2022. 12. 7.>

(3) The amount of sample and its collection method according to Paragraph 1, and other necessary details shall be determined and notified by the Minister of Ministry of Food and Drug Safety. <Amended 2022. 12. 7.>

Article 66 (Notification, etc. of National Lot Release)

(1) When the Minister of Ministry of Food and Drug Safety receives application of national lot release pursuant to Article 64, the result shall be notified to the applicant after examining and inspecting data concerning manufacturing and quality control of the medicinal product pursuant to criteria prescribed by the Minister of Ministry of Food and Drug Safety. In cases where the criteria are satisfied, a certificate of approval of national batch release provided in the Form No. 61 shall be issued.

(2) When acknowledged as necessary to facilitate national lot release pursuant to paragraph (1), the Minister of Ministry of Food and Drug Safety shall appoint essential provisions and inspect from criteria of paragraph (1).

(3) When national lot release is approved by the Minister of Ministry of Food and Drug Safety pursuant to paragraph (1) or (2), the results of national lot release shall be archived for 3 years. However, in case of the medicinal product of which the expiry date is longer than three years, the results of document shall be archived until the expiry date comes to an end.

(4) A person who receives the result of approval of national lot release pursuant to paragraph (1) may unseal medicinal products sealed pursuant to Article 65 (1).

Article 67 (Non-return of Samples)

Samples collected in accordance with Article 65 shall not be returned: Provided, That for equipment and device of which shape has not been changed even after testing, it shall be returned to the applicant 6 months after completion of testing, if the applicant requests the return.

Article 68 (Indication of National Lot Release Certificate)

(1) A person to whom the national lot release certificate pursuant to the latter part of Article 66 (1) shall not use the national lot release for advertisement: Provided, That if it is intended to indicate it on containers, packaging materials and others, the full text of the national lot release certificate shall be

indicated.

(2) When indicating the national lot release result pursuant to paragraph (1), the text of the national batch release certificate shall not be modified or "Government-guaranteed" or other similar expression shall not be used.

Article 69 (Labelling of Medicinal Products)

(1) Matters to be written on the container or the package of medicinal product referred to in subparagraph 10 of Article 56 (1) the Act shall be as the following subparagraphs: Provided, That matters falling under subparagraph 2 may be omitted only if such information is stated in an appended package leaflet and product name, a person who has obtained a marketing approval and name of importer may also be expressed in braille for the visually impaired people.

1. Appearance;
2. Efficacy and effectiveness;
3. Method of storage;
4. Deleted <Dec. 13, 2017>
5. Name and address of manufacturers when all manufacturing processes are contract-manufactured or all processes except weighing and packaging processes are contract-manufactured (contract giver or contract manufacturing and sales business person shall be marked as "contract client" and contract acceptor shall be marked as "manufacturer");
6. Name and address of manufacturer of producer for imported products or subdivided products of imported products (a person who imports or subdivides shall be marked as "importer" or "subdivider", and manufacturer of producer shall be "manufacturer");
7. "Standardized product" mark and origin (name of a country, etc.) for a standardized herbal medicine pursuant to subparagraph 5 of Article 62;
8. Name of product, name of a person who obtains marketing approval or importer, batch number, and use-by date or expiry date on PTP, foil packages, etc when medicinal products are packaged in such packages which enables to use a pill apiece. However, use-by date or expiry date may be marked as year-month unless it exceeds the use-by date or expiry date;
9. A bar code or an RFID tag prescribed by the Minister of Health and Welfare in consultation with the Minister of Ministry of Food and Drug Safety;
10. Name of substance, animal origin, and the part to be used when substances derived from animals (including additives) are used. However, the same shall not apply to the products which do not have risk to be infected by bovine spongiform encephalopathy during manufacturing process such as empty capsules.
11. Deleted <Dec. 13, 2017>
12. Letters of "medicinal products likely to cause drug abuse" for medicinal products likely to cause drug abuse, as notified by the Minister of Ministry of Food and Drug Safety;

13. Name of tar color if used;
14. Letters of "national batch release medicinal products" for every package unit for national batch release medicinal products pursuant to Article 63.

(2) Part of matters to be written may be omitted or substituted pursuant to each of the following subparagraphs in cases where a container or a package of which area is narrow so that part of matters to be written is not possible to be written pursuant to the proviso to the main part of Article 56 (1) of the Act.

1. For primary container or package of which matters of each subparagraph of Article 56 (1) of the Act are not possible to be written, matters to be written excluding name of product, batch number, expiry date or use-by date, name of a marketing authorization holder or importer may be omitted only in cases where the relevant matters are written on the package or the insert;
2. When matters referred to in Article 56 (1) 8 of the Act are written, "prescription drug" or "non-prescription drug" [non-prescription drug may be expressed as "over-the-counter (OTC) drug"] may be marked as "prescription" or "non-prescription" [non-prescription drug may be expressed as "over-the-counter (OTC) drug"] respectively;
3. When matters referred to in paragraph (1) 12 are written, "medicinal products likely to cause drug abuse" may be marked as "likely to cause drug abuse";
4. Letters of "refer to the insert for dosage and administration" and "refer to the insert for precautions" may be marked on the container or the package of the medicinal product falling under any of the following subparagraphs of which the usage, the dosage, or any other precautions necessary upon use or handling among matters of Article 56 (1) 9 are not possible to be written in cases where the relevant matters to be written are written on the insert only:
   A. Prescription drugs;
   B. Non-prescription drugs which are prescribed in accordance with the prescription by a doctor or a dentist and are marked as "for prescription";
   C. Medicinal products of which the amount is 50 g or 50 mL or less excluding tablets and capsules;
   D. Medicinal products packaged in one-dose package (for tablets and capsules only).
5. Notwithstanding subparagraph 4, for non-prescription drugs excluding medicinal products falling under the provisions of subparagraph B through D, "Directions for use and volume - Refer to appended package leaflet" and "Precautions - Refer to appended package leaflet" shall be indicated on the immediate container or package only if directions for use and volume and matters that require attention when using or handling medicinal products are specified on the immediate container or package.

(3) Matters to be written excluding each of the following subparagraphs may not be written on the containers managed pursuant to the High-Pressure Gas Safety Control Act pursuant to the proviso to the main part of Article 56 (1) of the Act.

1. Name and address of manufacturer;
2. Batch number and use-by date.

(4) Matters to be written excluding each of the following subparagraphs may not be written on the container or package of raw materials (excluding herbal substances) manufactured for the purpose to be used at the manufacturing site of medicinal products, etc. only pursuant to the proviso to the main part of Article 56 (1) of the Act.

1. Name of product;
2. Batch number, expiry date or use-by date;
3. Method of storage;
4. Name and address of manufacturer.

(5) Matters to be written excluding each of the following subparagraphs may not be written on the container or package of imported herbal substances pursuant to the proviso to the main part of Article 56 (1) of the Act.

1. Name of importer;
2. Name of product;
3. Weight or volume;
4. Origin (name of a country);
5. Inspection institution and date of inspection.

(6) Deleted <Oct. 28, 2016>

(7) Matters to be written of Article 56 (1) 9 of the Act may not be written on the container or package of medicinal products falling under any of the following subparagraphs pursuant to the proviso to the main part of Article 56 (1) of the Act. <Revised on Sep. 25, 2015, March 30, 2018>

1. Medicinal products for treating rare diseases which are directly imported by Chairperson of Korea Orphan and Essential Drug Center of Article 91 (1) of the Act, pursuant to subparagraph 3 of Article 58 upon the request for purchase by patients with rare diseases according to procedures as prescribed by the Minister of Ministry of Food and Drug Safety;
2. Radiopharmaceuticals which requires shield;
3. Blood products;
4. Empty capsules.

(8) When each of the following subparagraphs is written on the container or package of Non-prescription drugs pursuant to the proviso to the main part of Article 56 (1) of the Act, the contents may be summarized and only the part may be written pursuant to those prescribed by the Minister of Ministry of Food and Drug Safety. <Revised on Aug. 21, 2014>

1. Dosage and administration, any other precautions necessary upon use or handling;
2. Efficacy and Effectiveness.

(9) For medicinal products using herbal substances as raw materials, the name of the place of origin of the raw herbal substance can be displayed on the container or package pursuant to proviso other than

every subparagraph of Article 56 (1) of the Act. <Newly established, January 4, 2017>

(10) The "ingredients prescribed by the Ordinance of the Prime Minister" referred to in the proviso to Article 56 (1) 7 of the Act shall mean the ingredients in the following subparagraph: <Newly established, Dec. 13, 2017>

1. Ingredients containing small amounts other than preservatives;
2. Among ingredients listed in the certificate of marketing approval and product notification pursuant to Article 13, those other than the names of ingredients which are listed in composition and that are prescribed through separate specifications, etc.

Article 70 (Description of Appended Package Leaflet)

(1) Matters to be written on package leaflet pursuant to Article 58 (4) of the Act shall include matters falling under the following subparagraphs:

1. Article 56 (1) 1, 2, 4 to 7, 9 and 10 of the Act (excluding matters referred to in Article 69 (1) 9);
2. Letters of "prescription drug" or "non-prescription drug" [non-prescription drug may be expressed as "over-the-counter (OTC) drug"];
3. Letters of "medicinal products likely to cause drug abuse";
4. Contents that medicinal products which have passed use-by date or expiry date, or are deteriorated, degenerated, contaminated, or damaged are exchanged to pharmacy founders, over-the-counter drug sellers and sellers of medicinal products only, and exchange method; and
5. Date of preparation or date of final Revised on of package leaflet.

(2) Deleted <Oct. 28, 2016>.

(3) Notwithstanding the provision of Paragraph (1), when matters falling under each subparagraph of Paragraph (1) (In the case of herbal substances, refers to the matters under each subparagraph Article 69 (5)) are written on the containers or packages, a package leaflet may be omitted. <Revised on June 30, 2016>

Article 71 (Precautions in Labelling)

Precautions that have to be taken when preparing labelling information for containers, packaging materials or accompanying documents of medicinal products pursuant to Article 59 of the Act are as follows:

1. Address under Article 56 (1) 1 of the Act and Article 69 (1) 5 and 6 of this Regulation (for corporations, the address of principal office) may include only the name of city or province (for foreign countries, only the country name), and full address thereof shall be specifically expressed on at least one of a container, packaging or package leaflet.
2. The bar code or electronic tag pursuant to Article 69 (1) 9 shall be readable by a scanner and it shall be correctly indicated to assure that the relevant medicinal product is not recognized as

another one.

3. The amount weight of the medicinal product content shall exclude the weight of the relevant container or packaging material.
4. Only the objective product characteristics within the authorized scope shall be described.
5. Quality standard of active pharmaceutical ingredient shall be indicated.
6. Pharmacological action that may give false or exaggerated impression on efficacy and effectiveness shall not be indicated.
7. For combination products, the efficacy or effectiveness of each substance and related diseases shall not be listed and, when describing the synergistic or additive effect, it shall be based on objective supporting data.
8. Precautions in use shall be clearly described for easy identification.
9. Exceptional data shall not be described as if it were generally-recognized fact.
10. When explaining or referencing animal data, the type of animal used shall be indicated and any expression showing that data from studies in animals guarantees the safety and efficacy in human bodies shall be avoided.
11. Description of data on comparison with other medicinal products shall be based on objective supporting data and the medicinal product subject to comparison shall be described in generic name of its active pharmaceutical ingredient.
12. Statements pursuant to Article 56 (1) 8 of the Act and Article 70 (1) 2 of this Regulations shall be indicated to allow easy identification.
13. For injections with only one administration method, the administration method shall be described in bold on the containers in Korean or English abbreviations (such as "For Intravenous Injection", "For Intravenous Inj.", "IV", "For Intramuscular Injection", "IM"): Provided, That this shall not apply to infusions.
14. Other precautions, such as font size, line spacing, description method, and exceptions, as notified by the Minister of Ministry of Food and Drug Safety shall be followed.

Article 71-2 (Data submission for investigation of unauthorized marketing of pharmaceutical)

(1) The Minister of Ministry of Food and Drug Safety may request the following scope of data to telecommunication service provider(hereinafter in the ‘telecommunication service provider’) to investigate unauthorized marketing of pharmaceutical pursuant to the former part of Article 61(2)(2).

1. Data concerning personal information of person who committed a violation
2. Data concerning business office of person who committed a violation
3. Data concerning content for violation
4. Besides the matters mentioned above, the matters which the Minister of Ministry of Food and Drug Safety deems necessary to investigate unauthorized marketing of pharmaceutical.

(2) The Minister of Ministry of Food and Drug Safety shall include the following document(electronic document

is included) where the Minister requests the telecommunication service provider to submit the data pursuant to Article 61(2)(2).

1. Matter concerning ground law for data submission
2. Matter concerning scope of submitted data
3. Matter concerning method and deadline of data submission
4. Besides the matters mentioned above, the matters which the Minister of Ministry of Food and Drug Safety deems necessary or equivalent thereto.

(3) The document(electronic document is included) which includes the following matters shall be submitted where the telecommunication service provider notify the Minister of Ministry of Food and Drug Safety of the fact of violation pursuant to Article 61(2)(3).

1. Content concerning fact of violation
2. Internet address which violation occurred
3. Evidentiary data for fact of violation

[Newly established 6 Dec, 2019]

Article 72 (Sealing)

Container or package of medicinal products pursuant to Article 63 of the Act shall not be openable unless the sealing of container or package is torn off and it shall not be easily restorable after opening.

Article 73 (Products Subject to Use Safety Container and Package and Criteria)

(1) Medicinal products that have to be manufactured using safety container and .package in accordance with Article 64 of the Act shall be orally-administered products that fall into one of the following subparagraphs: Provided, That this shall not apply to medicinal products used in preparation according to the medical doctor's prescription.

1. Medicinal products containing not less than 30 mg of iron substance in one dose;
2. Medicinal products containing aspirin substance;
3. Medicinal products of which individual package (meaning package of collection of individual pills, individual bottle, or other kinds of package containing small amount of medicinal products) contains more than 1 g of acetaminophen;
4. Medicinal products of which individual package contains more than 1 g of ibuprofen;
5. Oral liquids for pediatric use;
6. Medicinal products of which individual package contains more than 0.045 mg of loperamide;
7. Medicinal products containing naproxen and its salts of which individual package contains more than 250 mg of naproxen substance;
8. Medicinal products containing ketoprofen and its salts of which individual package contains more than 50 mg of ketoprofen substance;
9. Medicinal products of which individual package contains more than 66 mg of

diphenhydramine and its salts.

(2) A person who holds the marketing approval or import approval for medicinal products pursuant to paragraph (1) shall, when manufacturing or importing such medicinal products, use the containers or packages designed and devised to assure that it is difficult for children of below age 5 to open them within a certain time, as notified by the Minister of Food and Drug Safety. <Revised on March 30, 2018>

Article 74 (Labelling of Quasi-Drug Containers, etc.)

(1) If the area of containers to which products are put in directly or on packaging all the items listed in each subparagraph of Article 65 (1) of the Act cannot be described pursuant to proviso other than every subparagraph of Article 65 (1) of the Act, a part of the description may be omitted or replaced with other descriptions in the manner specified in the following subparagraphs: <Revised on Dec. 13, 2017>

1. If the items listed in each subparagraph of Article 65 (1) of the Act are described on the outside or packaging of a container, or in the attached document: Items other than the name of the product, the name of the manufacturer or importer, the lot number, the use by date(shall be omitted. However, in the case of items corresponding to the Item A of the Subparagraph 7 of the Article 2 of the law, written matters except for name of product name of manufacturer or importer can be omitted.
2. If the items to be described under Paragraph (3) 3 or 4 are described on the outside or packaging of a container, or in the attached document: In the containers to which products are put in directly or in the part that packages the product directly, replace with a statement such as "dosage and administration – refer to the external containers, packaging or attached documents" or "precautions - refer to the external container, packaging or attached document"

(2) The "ingredients prescribed by the Ordinance of the Prime Minister" referred to in the proviso to Article 65 (1) 5 of the Act shall mean the ingredients in the following subparagraph: <Newly established, Dec. 13, 2017>

1. Ingredients containing small amounts other than preservatives;
2. Among ingredients listed and the amount shown in the certificate of marketing approval and product notification pursuant to Article 13, those other than the names of ingredients which are listed in composition and that are prescribed through separate specifications, etc.

(3) Matters to be indicated on container or package of quasi-drugs (except for the products falling under item A of subparagraph 7 of Article 2 of the Act) pursuant Article 65 (1) 8 shall be as follows: <Revised on Oct. 28, 2016, Dec. 13, 2017>

1. Deleted <Dec. 13, 2017>
2. Efficacy and effectiveness;
3. Dosage and administration;
4. Precautions;

5. If any substance of animal origin (including excipients) is used, the name of the substance, source animal and its parts used. However, for substances without the risk of bovine spongiform encephalopathy when considering the process of manufacture, such as empty capsules, etc., this information shall not be required.
6. If all manufacturing processes are contracted to another company or if all production processes except weighing of raw materials and packing operations are contracted, the name and address of the manufacturer (the contractor shall be marked as "contract client," and the contract acceptor as "manufacturer");
7. For imported products or if subdivided after being imported, the name and address of the manufacturer in the producing country (a person who imports or subdivides shall be marked as "importer" or "subdivider", and manufacturer of producer shall be "manufacturer");
8. For a smoking-cessation aid, following information specified by the Minister of Ministry of Food and Drug Safety
   A. Warning statement;
   B. Information about particular ingredients such as tar and carbon monoxide, etc.
9. Deleted <Dec. 13, 2017>
10. Name of the tar pigment, if used.

Article74-2(Mentioned matters of attached document of Quasi-drugs) Matters to be written in the attached document according to the subparagraph 4 of the Article 65-3 are as follows.

(1) Matters except for Subparagraph 4 and 8 among the matters of each subparagraph of the Paragraph 1 of the Article 65.

(2) Exchange place, contact information and exchange method regarding quasi-drugs whose expiration date is over or that are degenerated · deteriorated · polluted or damaged

(3) Date of writing or final revision of attached documents

[Newly established in this Article Oct. 25, 2018]

Article 75 (Precautions in Labelling of Quasi-Drugs)

Precautions that have to be taken when preparing labelling information for containers, packaging materials or package leaflet of quasi-drugs pursuant to Article 65-2 of the Act are as follows;

1. The amount of the quasi-drug content shall not include the weight of a container or packaging material (except those falling under subparagraph 7 A of the Act).
2. Only the objective product characteristics within the authorized scope shall be described.
3. Pharmacological action that may give false or exaggerated impression on efficacy and effectiveness shall not be indicated.
4. Quality standard of active pharmaceutical ingredient shall be indicated (limiting to oral liquids, oral solids, ointments, cataplasma, and topical spray PAS).

5. Precautions in use shall be clearly described for easy identification.
6. Exceptional data shall not be described as if it were generally-recognized fact.
7. When explaining or referencing animal data, the type of animal used shall be indicated and any expression showing that data from studies in animals guarantees the safety and efficacy in human bodies shall be avoided.
8. Description of data on comparison with other quasi-drugs shall be based on objective supporting data and the quasi-drug subject to comparison shall be described in generic name of its active substance.
9. Statements pursuant to Article 65 (1) 7 of the Act shall be indicated to allow easy identification.
10. Other description method and exceptions, as notified by the Minister of Ministry of Food and Drug Safety shall be followed.

Article 76 (Information Indicated on Containers, etc. for Delivery to Public Organizations)

The containers or packages for medicinal products and others approved with the condition of delivery to public organizations shall include the phrase "For Delivery", in addition to information pursuant to the Act and this regulation.

Article 77 (Description of Information)

Information pursuant to Article 56 to Article 58, and Article 65 of the Act shall be described in Korean. However, the Chinese characters or other foreign languages in the same size of the Korean description may be additionally expressed at the same time. For medicinal products, etc. to be exported, the information may be described in the language of the relevant importing country.

Article 78 (Scope of Advertisement of Medicinal Products, etc.)

(1) The "cases prescribed by the Ordinance of the Prime Minister" referred to in the proviso other than every subparagraph of Article 68 (6) of the Act shall mean a case falling under any of the following subparagraphs: <Revised on April 25, 2018>
1. Advertisement of medicinal products for prevention of infectious diseases referred to in Subparagraphs 2 through 12 of Article 2 of the Infectious Disease Control and Prevention Act;
2. Advertisement on media specializing in medicines for medical or pharmacological experts;
3. Advertisement using media or means of academic nature for medical or pharmacological experts.

(2) Media or means for advertisement of medicinal products, etc. pursuant to Article 68 (7) of the Act shall be as follows: <Revised on April 25, 2018>
1. Newspaper, broadcasting or magazine;
2. Flyer, pamphlet, specimen or admission ticket;
3. Internet or computer communication network;
4. Poster, signboard, neon sign, advertising balloon or electric board;

5. Video, record, book, publication, movie or play;
6. Advertisement by visit or demonstration;
7. Containers or packages of their own medicinal products, etc. or of other products (excluding information that shall be described on containers, packages, etc. of their own medicinal products, etc. pursuant to Articles 56 to 58 and Article 65 of the Act);
8. Other media or means similar to those as specified in the Subparagraphs 1 to 7.

(3) Matters to be followed when advertising medicinal products, etc. shall be as shown in Annex 7.

Article 79 (Scope of Advertisement Deliberation)

(1) If a medicinal product manufacturer, a marketing approval holder or an importer who intends to apply for deliberation of advertisement of medicinal products in accordance with Article 68-2 (1) of the Act (hereinafter referred to as "advertisement applicant") intends to advertise medicinal products using one of the following media or means, he/she shall get deliberation by an organization entrusted with deliberation of advertisement of medicinal products in accordance with Article 68-2 (2) of the Act and Article 32-5 of the Enforcement Decree (hereinafter referred to as "advertisement deliberation organization").

1. Newspaper and Internet newspaper pursuant to Article 2 of the Act on the Promotion of Newspapers, Etc. and periodicals pursuant to Article 2 of the Act on Promotion of Periodicals, including Magazines: Provided, That this shall not apply to advertisement using media or means of academic nature or delivering professional information to medical or pharmacological experts.
2. Television and radio broadcasting pursuant to subparagraph 1 of Article 2 of the Broadcasting Act;
3. Internet pursuant to subparagraph 2 of Article 2 of the Enforcement Decree of the Act on Fair Labelling and Advertising;
4. Other media or means as notified by the Minister of Ministry of Food and Drug Safety.

(2) Notwithstanding the provisions of paragraph (1), if the advertisement applicant intends to advertise only the advertisement applicant's company name, approved or registered product name, efficacy and effectiveness, and dosage and administration method using media under the main body of paragraph (1), subparagraph 1, he/she may make advertisement without deliberation by the advertisement deliberation organization.

(3) If the advertisement applicant intends to make advertisement of medicinal products pursuant to paragraph (2), he/she shall inform the advertisement deliberation organization of the fact in advance. In such instance, if the advertisement deliberation organization considers that the relevant advertisement has to be deliberated, the advertisement deliberation organization shall immediately inform the advertisement applicant of the fact to assure that deliberation of the relevant advertisement is conducted.

Article 80 (Advertisement Deliberation Procedure, etc.)

(1) The advertisement applicant shall submit to the advertisement deliberation organization the application for deliberation of advertisement of medicinal products of Form No. 62, together with documents falling under the following subparagraphs:

1. One copy of advertisement of the medicinal product;
2. One copy of description of the medicinal product.

(2) On receipt of the application of the paragraph (1), the advertisement deliberation organization shall deliberate it at the medicinal product advertisement deliberation committee ("deliberation committee") pursuant to Article 83, decide on the relevant advertisement of medicinal product and notify the deliberation result to the advertisement applicant within 10 days from the date of application: Provided, That if the notification of deliberation result cannot be made within the above period owing to unavoidable reason, the reason for delay and the planned deadline shall be notified to the advertisement applicant.

(3) If the applicant has objection to the deliberation result notified under paragraph (2), the applicant may submit the formal objection of Form No. 62 describing the intention and reason for such objection to the advertisement deliberation organization within 10 days from the date when the notification of deliberation result is received.

(4) On receipt of the formal objection pursuant to paragraph (3), the advertisement deliberation organization shall deliberate it again and notify the result from deliberation of the formal objection to the applicant within 10 days after receiving the formal objection.

(5) A person who submit an application under Paragraph (1) shall pay the fee prescribed and notified by the Minister of Ministry of Food and Drug Safety. <Newly established, Dec. 13, 2017>

[Title Revised on Dec. 13, 2017]

Article 81 (Change in Deliberated Advertisement)

(1) If a person who completed the deliberation of advertisement of medicinal products pursuant to Article 80 intends to change the matters of deliberated advertisement, such changed advertisement shall be deliberated in accordance with Article 80: Provided, That deliberation may not be required if the advertisement's some phrases are changed or deleted within the scope of not changing the contents of the advertisement.

(2) A person who intends to advertise medicinal products pursuant to the proviso of paragraph (1) shall inform the advertisement deliberation organization of the fact in advance. In such instance, if the advertisement deliberation organization considers that the notified advertisement falls into substantial change of advertisement, the advertisement deliberation organization shall immediately inform the person who intends advertisement of the fact to assure that deliberation of the relevant advertisement shall be conducted.

Article 82 (Indication of Deliberation Result)

If the advertisement applicant intends to advertise medicinal products as deliberated pursuant to Article 80 and Article 81, the completion of deliberation shall be indicated on the advertisement.

Article 83 (Organization and Operation of Medicinal Products Advertisement Deliberation Committee)

(1) The advertisement deliberation organization shall establish and operate the medicinal product advertisement deliberation committee.

(2) The deliberation committee shall consist of between not less than 10 members and not more than 20 members, including one chairperson and two vice chairpersons and those falling under subparagraphs 2 through 4 of paragraph (3) shall hold a majority in the deliberation committee.

(3) The head of the advertisement deliberation organization shall appoint members among those falling under the following subparagraphs and the chairperson and vice chairpersons shall be elected by committee from among its members.

1. Employees belonging to member companies of the advertisement deliberation organization;
2. Persons recommended by Consumers' organization in accordance with the Framework Act on Consumers or by the head of the private organization in accordance with the Assistance for Non-Profit, Non-Governmental Organizations Act;
3. Persons recommended by the head of medicinal products-related association and organization;
4. Others with sufficient knowledge and experience in public health.

(4) The member's term of committee shall be one year and they may serve consecutive terms: Provided, that the member under subparagraph 1 of paragraph (3) shall serve consecutive terms only for once.

(5) The head of the advertisement deliberation organization shall report to the Minister of Ministry of Food and Drug Safety the results from deliberation of medicinal products advertisements and any formal objections within 20 days after the end of each quarter on a quarterly basis.

(6) Matters other than prescribed in the provisions of paragraph (1) to (5), those necessary for organization and operation of the deliberation committee shall be determined by the head of the advertisement deliberation organization with the approval of the committee.

Article 84 (Reporting on Side Effects, etc.)

(1) "Cases concerning safety and efficacy prescribed by the Ordinance of the Prime Minister" of Article 68-8 (1) of the Act shall refer cases that undesirable or unintended signs, symptoms or diseases occur and shall not be limited to the cases where the cause and effect relationship with the relevant medicinal product is clarified. <Revised on Oct. 28, 2016>

(2) "Cases of serious diseases, disabilities, death prescribed by the Ordinance of the Prime Minister" of Article 68-8 (2) of the Act shall refer any case falling under the following subparagraphs: <Revised on Oct. 28, 2016>

1. Cases which cause death or threaten a person's life;
2. Cases which require hospitalization or the extension of hospitalization period;
3. Cases which cause continuous or serious disabilities or malfunction;
4. Cases which cause congenital deformity or abnormality;
5. Cases which require treatment due to medically serious situations such as drug dependency or abuse, or hematodyscrasia other than the cases falling under subparagraphs 1 to 4.

Article 84-2 (Qualifications, Scope of Duties, etc. of Pharmacoepidemiological Investigators)

(1) A person who falls into one of the following sub-paragraphs shall be appointed or commissioned as a pharmacoepidemiological investigator under Article 68-12 (1) of the Act:
1. An employee in charge of investigating and identifying the causal relationship of drug side effects at Korea Institute of Drug Safety & Risk Management;
2. A public health doctor pursuant to Article 2 of the Act on the Special Measures for Public Health and Medical Services;
3. A medical doctor, dentist or oriental medicinal doctor pursuant to Article 2 (1) of the Medical Service Act;
4. A pharmacist or oriental pharmacist pursuant to Article 2, Sub-paragraph 2 of the Act;
5. An expert in the fields relating to side effects of medicinal products, such as medicinal product-related accidents, etc.

(2) The head of the KIDS may provide such commissioned pharmacoepidemiological investigator with monetary allowance and travel expense within the scope of the budget.

(3) For one of the following situations, the pharmacoepidemiological investigator shall investigate and identify the causal relationship between medicinal products and side effects:
1. If a medicinal product-related accident involving serious adverse drug reactions such as disease, disability or death occurs;
2. If numerous adverse events are observed in a specific area or in a specific period;
3. If there is a request for aid for damages arising from side effects of a medicinal product pursuant to Article 86-4 (1) of the Act;
4. Other situations in which the Minister of Ministry of Food and Drug Safety determines that there is a need for investigation and identification of causal relationship between medicinal products and side effects.

(4) The certificate proving the identity of the pharmacoepidemiological investigator shall be issued using Form No. 85.

[This Article is newly established. Oct. 10, 2014]

Article 85 (Quality Management of Medicinal Products, etc.)

(1) In accordance with Article 69 of the Act, the Minister of Ministry of Food and Drug Safety may

prescribe a management method of standardized products necessary for quality examination, collecting and examination method of test samples, issuance of examination results, countermeasures according to the examination results and other details in order to verify if the quality of medicinal products, etc. is appropriate for manufacture, importation and sale.

(2) The Minister of Ministry of Food and Drug Safety may request Mayors and Provincial Governors necessary matters such as collecting, examination and etc. for the quality control of medicinal products, etc.

Article 86 (Collection, etc.)

(1) In case where a pharmaceutical inspector collects products or medicinal products, etc. pursuant to Article 69 (1) 3 of the Act, a certificate of collection of From No. 63 shall be issued to the owner of the relevant products or medicinal products, etc. subject to collection.

(2) A pharmaceutical inspector may take actions of sealing or stamping products or medicinal products, etc. falling under Article 71 (1) of the Act.

Article 87 (Scope of Duties of Pharmaceutical Inspectors)

Scope of duties of pharmaceutical inspectors pursuant to Article 69 (3) of the Act shall be as follows: <Revised on Aug. 20, 2014, March 13, 2015>

1. Pharmaceutical inspectors of the Ministry of Food and Drug Safety or the Regional Korea Food and Drug Administration shall conduct pharmaceutical surveillance, collections and tests of medicinal products, etc. concerning manufacturers, importers, contract manufacturing and sales business persons of medicinal products, etc., registered patentee, patentee, etc. of a listed drug, clinical trial institutions, clinical trial sample analysis institution, non-clinical trial conducting institutions and their workplace as well as the relevant person of clinical trials, bioequivalent studies, non-clinical trials,, pharmacist's surveillance for personnel related to quality inspection, collection and inspection of medicinal products, and review and management of medicinal products with approval for exclusive marketing product.: Provided, That when ordered by the Minister of Ministry of Food and Drug Safety with request from the Minister of Health and Welfare or by the Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS, they may conduct duties referred to in the main part of subparagraph 2.
2. Pharmaceutical inspectors of special metropolitan city, metropolitan cities, provinces, special autonomous provinces or Si/Gun/Gus shall conduct pharmaceutical inspections, collections and tests of medicinal products, etc. concerning pharmacy founders, over-the-counter drugs sellers, medical institution founders, any other sellers of medicinal products, etc. and their workplace: Provided, That they may conduct duties referred to in the main part of subparagraph 1 when the Minister of Ministry of Food and Drug Safety orders the Special metropolitan City, Metropolitan Cities, Dos and Special Self-Governing Province or a pharmaceutical inspectors belonging to Si/Gun/Gus and when deemed necessary by the Minister of Health and Welfare, pharmaceutical

inspectors belonging to the Ministry of Health and Welfare may conduct the duties referred to in the main part of subparagraph

Article 87-2 (Report of Agreement, etc.)(1) The report of agreement pursuant to Article 69-3 of the Act shall be in accordance with the report of agreement in Form 63-2 (including the report in an electronic form).

(2) The “matters prescribed by the Ordinance of the Prime Minister" referred to in the part other than every item of Article 69 (3) of the Act shall means the following:

1. The parties to the agreement;
2. Details of the agreement;
3. Time of the agreement;
4. Information about medicinal products related to the agreement

[This Article is newly established. Sep. 25, 2015]

Article 87-3 (Entry and Exit, Examination for Foreign Manufacturer) (1) The Minister of Ministry of Food and Drug Safety shall inform an importer, manager from the foreign manufacturer or exporting country of the following matters in written form (electronic document is included) 20 days before performing said entry and exit・examination, if entry and exit・examination for the foreign manufacturer are performed according to Article 69(5)(1).

1. The scope of entry and exit・examination

2. The period of entry and exit・examination

3. The human resources for entry and exit・examination

4. Besides the matters above, the matters which the Minister of Ministry of Food and Drug Safety deems necessary to effectively perform entry and exit・examination for the foreign manufacturers.

(2) The Minister of Ministry of Food and Drug Safety shall inform an importer, manager from the foreign manufacturer or exporting country of the following matters in written form (electronic document is included), if the Minister take import suspension(hereinafter refer to ‘import suspension,.etc’) according to Article 69(5)(2).

1. Matters to measure

2. Reason to measure

3. Date to measure

4. Besides the matters mentioned above, the matters which the Minister of Ministry of Food and Drug Safety deems necessary to take import suspension.

(3) The Minister of Ministry of Food and Drug Safety shall inform an importer, manager from the foreign manufacturer or exporting country of the following matters in written form (electronic document is included),

if the Minister revokes import suspension according to Article 69(5)(3).

1. Matters to revocation
2. Reason to revocation
3. Date to revoke
4. Besides the matters above, the matters which the Minister of Ministry of Food and Drug Safety deems necessary to revoke import suspension.

[Newly established 6 Dec, 2019]

Article 88 (Order of Recall and Scrapping, etc.)

(1) Pursuant to Article 71 (2) of the Act, when deemed that any medicinal products, etc. actually harms or is likely to harm public health, the Commissioner of the Regional FDS, a Mayor/Do Governor, or the head of a Si/Gun/Gu shall evaluate the grades of harms of the medicinal products, etc. pursuant to Article 50 (2) and order the recall obligator to recall, scrap or other necessary actions according to the results of evaluation.

(2) The provision of Article 89 (1) shall apply mutatis mutandis to the methods of announcement pursuant to Article 72 (2) of the Act.

Article 89 (Notification, etc. of Recall Plan)

(1) The recall obligator of medicinal products, etc. subject to recall shall notify the recall strategy pursuant to each of the following criteria when the notification is ordered pursuant to Article 72 (1) of the Act.

1. Class 1: Broadcasting, daily newspaper, or the mass media which is equal to or higher than such media;
2. Class 2: Medical or pharmaceutical journal or a medium which is equal to or higher than such journals;
3. Class 3: The homepage of the relevant firm or a medium which is equal to or higher than its homepage.

(2) The Commissioner of the Regional FDS may publish the company name of the recall obligator of medicinal products, etc. subject to recall, product name, batch number, manufacturing date, use-by date or expiry date, and reason for recall.

(3) The recall obligator of medicinal products, etc. subject to recall shall notify the recall strategy to sellers, pharmacy founders, over-the-counter drugs sellers or medical institution founders who handle medicinal products, etc. subject to recall (hereinafter referred to as "handlers of medicinal products, etc. subject to recall") through visit, mail, phone call, telegram, electronic mail, fax, and mass media, and retain data which can prove the notification for two years from the date of the

completion of recall.

(4) Handlers of medicinal products, etc. subject to recall who receive the recall strategy pursuant to paragraph (3) shall return medicinal products, etc. subject to recall, fill in the recall response provided in the Form No. 64 and send it to the recall obligator of medicinal products, etc. subject to recall.

(5) The Minister of Ministry of Food and Drug Safety may develop and operate a computer program which provides information, etc. of medicinal products, etc. subject to recall and recommend handlers etc. of medicinal products, etc. subject to recall to equip with it.

(6) "Hazards prescribed by the Ordinance of the Prime Minister" referred in the proviso of Article 72 (1) of the Act shall be the hazards falling under the Article 50 (2) 1 or 2.

(7) The recall obligator who declares recall strategy pursuant to paragraph (1) shall submit the result of declaration including each of the following matters to the Commissioner of the Regional FDS without delay.

1. Date of announcement;
2. Media of announcement;
3. Number of announcement;
4. Copy of announcement or the contents.

(8) Details concerning contents of announcement, method of announcement, period of announcement and notification etc. of recall strategy pursuant to paragraphs (1) to (7) shall be announced by the Minister of Ministry of Food and Drug Safety.

Article 90 (Scrapping, etc. of Recalled Products)

(1) The recall obligator of medicinal products, etc. subject to recall shall scrap recalled or returned products or take other actions to prevent any hazard, and shall prepare the evaluation report provided in the Form No. 65.

(2) In cases where the scrapping pursuant to paragraph (1) is conducted, the recall obligator of medicinal products, etc. subject to recall shall submit a scrapping application form provided in the Form No. 66 to the competent mayor or provincial governor, scrap the medicinal products, etc. pursuant to the legislation concerning environment with a relevant public official attendance, and fill in and retain the scrapping confirmation letter provided in the Form No. 67 for 2 years.

(3) The recall obligator of medicinal products, etc. subject to recall shall submit the recall completion report provided in the Form No. 68 with each of following documents to the Commissioner of the Regional FDS upon the completion of the recall.

1. A copy of the recall confirmation letter provided in the Form No. 64;
2. A copy of the evaluation report provided in the Form No. 65;
3. A copy of a scrapping application form provided in Form No. 66 and a copy of the scrapping confirmation letter provided in Form No. 67 (only in cases the scrapping is conducted).

(4) When the recall completion report pursuant to paragraph (3) is received, the Commissioner of the

Regional FDS shall take actions as prescribed in each of the following subparagraphs:

1. To confirm that the recall is completed and to notify it in writing to the recall obligator when it is deemed that the recall of the medicinal products, etc. subject to recall has been appropriately conducted;
2. To order the recall obligator to take additional actions necessary for the recall when it is deemed that the recall has not been completed effectively.

(5) The competent mayor or provincial governor shall report the completion of scrapping pursuant to paragraph (2) to the Commissioner of the Regional FDS upon the completion.

(6) The Minister of Ministry of Food and Drug Safety may disclose the production and import volume, sales volume, amount of inventory for distribution, amount of recall, etc. of medicinal products subject to recall on the internet homepage pursuant to relevant laws and regulations <Newly established, March 30, 2018>

(7) Details concerning hazard prevention actions of the recall obligator, scrapping procedures, preparation of evaluation report, confirmation and notification of the completion of recall, etc. subject to recall, etc. pursuant to paragraphs (1) to (6) shall be prescribed and announced by the Minister of Ministry of Food and Drug Safety. <Revised on March 30, 2018>

Article 91 Deleted <Aug. 20, 2014>

Article 92 Deleted <March 20, 2014>

Article 93 Deleted <March 20, 2014>

Article 94 Deleted <March 20, 2014>

Article 95 (Criteria for Administrative Dispositions)

Criteria for administrative dispositions pursuant to Article 76 (3) and Article 76-2 of the Act shall be pursuant to Annex 8.

Article 96 (Reissuance of Certificate of License, etc.)

(1) When a manufacturer, an importer and a contract manufacturing and sales business person of medicinal products, etc., a person who prepares pharmacy medications or dispensary medications, a person who received approval of clinical trial plan, a clinical trial institution, clinical trial sample analysis institution, educational institutions for clinical trials, or a non-clinical trial institution loses or damages its certificate of license, register, approval, report, completion of report or designation, or the letter of compliance (hereinafter referred to as "certificate of license, etc." in this Article and Article 97), or when an entered matter of certificate of license, etc. is changed, a manufacturer, an importer and a contract manufacturing and sales business person, those who received approval for clinical trial

plan · clinical trial institution · clinical trial sample analysis institution or non-clinical trial institution of medicinal products, etc., shall submit the reissuance application of the attached from No. 72 (including an electronic form) together with damaged or ruined certificate to the Minister of Ministry of Food and Drug Safety (or to the Commissioner of the Regional FDS in case of the reissuance of the certificate of approval or registration of manufacturing business of medicinal products, etc., the certificate of register of contract manufacturing and sales business, the certificate of register of importing business, the certificate of marketing approval of manufacture, sale and importation of medicinal products required to prove their bioequivalence, the certificate of marketing approval of manufacture, sale and importation of quasi-drugs which are not subject to review of safety of efficacy and the certificate of notification of manufacture, sale and importation of medicinal products, the letter of GMP compliance for medicinal products, etc.) and a person who prepares pharmacy medications or dispensary medications shall submit the reissuance application of the attached from No. 72 (including an electronic form) together with damaged or ruined certificate to heads of Sis/Guns/Gus (and a person who prepares dispensary medications pursuant to the proviso of Article (1) of the Act submit to Mayors/Do Governors) respectively. <Revised on Aug. 20, 2014, Sep. 25, 2015, Dec. 13, 2017, March 30, 2018>

(2) When a certificate of license, etc. is reissued pursuant to paragraph (1), the Minister of Ministry of Food and Drug Safety, the Commissioner of the Regional FDS, a mayor/provincial governor or the head of a Si/Gun/Gu shall put the reason for reissuance on the relevant register.

(3) When the lost certificate of license etc. is found after receiving reissued certificate of license etc. pursuant to paragraph (2), the applicant shall return it to the Minister of Food and Drug Safety, the Commissioner of the Regional FDS, a mayor/provincial governor or the head of a Si/Gun/Gu without delay.

(4) A person who applies for the reissuance of certificate of license, etc. shall pay a fee as prescribed by the Minister of Ministry of Food and Drug Safety.

Article 97 (Return of Approval Certificate, etc.)

(1) If a medicinal product, etc. manufacturer, importer or a contract manufacturing and sales business person, a person who obtained permission of clinical trial plan, a clinical trial institution, a clinical trial sample analysis institution or a non-clinical trial institution is subjected to cancellation of its registration, approval and permission or designation, or shutdown of its contract manufacture and distribution site and manufacturing site (limiting to the business registered in accordance with Article 31 (3) and (4) of the Act; this limitation also applies to paragraph (2)), in accordance with Article 76 or Article 76-2 of the Act, the relevant permissions shall be returned to the Minister of Ministry of Food and Drug Safety within 10 days from the date of such disposition (or to the Commissioner of the Regional FDS in case of the reissuance of the certificate of approval or registration of manufacturing

business of medicinal products, etc., the certificate of register of contract manufacturing and sales business, the certificate of register of importing business, the certificate of marketing approval of manufacture, sale and importation of medicinal products required to prove their bioequivalence, the certificate of marketing approval of manufacture, sale and importation of quasi-drugs which are not subject to review of safety of efficacy and the certificate of notification of manufacture, sale and importation of medicinal products, etc.). However, when returning the certificate of approval or certificate of register for manufacturing business of medicinal products, etc., the letter of GMP compliance for medicinal products shall also be returned. <Revised on Aug. 20, 2014, Sep. 25, 2015, March 30, 2018 >

(2) If a medicinal product manufacturer, contract manufacturer and distributor, importer of medicinal products, etc. a person who obtains permission of clinical trial plan <deleted>, a clinical trial institution, clinical trial sample analysis institution or a non-clinical trial institution is subjected to cancellation of its registration, approval, permission or designation, or shutdown of its a contract manufacturing and sales business site, manufacturing site, or suspension of business operations in accordance with Article 76 or Article 76-2 of the Act, the Minister of Ministry of Food and Drug Safety or the Commissioner of the Regional FDS shall document the information on such disposition in the relevant registration, approval or register log. <Revised on Aug. 20, 2014, Sep. 25, 2015>

Article 98 (Qualification of Pharmaceutical Inspectors)

Pharmaceutical inspectors pursuant to Article 78 of the Act shall be designated among persons falling under any of the following subparagraphs:

1. a pharmacist or an oriental pharmacist;
2. a person who has expertise and experience concerning pharmaceutical affairs and acknowledged by the Minister of Health and Welfare, the Minister of Food and Drug Safety, a mayor/provincial governor, or the head of a Si/Gun/Gu.

Article 99 (Certificate of Pharmaceutical Inspectors)

The certificate which certifies the position of pharmaceutical inspectors shall be pursuant to the format provided in the Form No. 73.

Article 100 (Renewal of Permissions)

(1) The approval or register granted to the manufacturer, importer or a contract manufacturing and sales business person of medicinal products in accordance with Article 80 of the Act shall be renewed periodically as deemed necessary and determined by the Commissioner of the Minister of Ministry of Food and Drug Safety (or to the Commissioner of the Regional FDS in case of the renewal of the certificate of approval or registration of manufacturing business of medicinal products, etc., the certificate of register of contract manufacturing and sales business, the certificate of register of

importing business, the certificate of marketing approval of manufacture, sale and importation of medicinal products required to prove their bioequivalence, the certificate of marketing approval of manufacture, sale and importation of quasi-drugs which are not subject to review of safety of efficacy and the certificate of notification of manufacture, sale and importation of medicinal products, etc.) <Revised on Sep. 25, 2015>

(2) When renewal periods are decided pursuant to paragraph (1), the Minister of Food and Drug Safety or the Commissioner of the Regional FDS shall make public announcement without delay.

(3) A person who intends to renew the approval and registration pursuant to paragraph (1) shall submit the renewal application of Form No. 74 (including electronic application) with the relevant approval and registration or register attached, to the Minister of Food and Drug Safety (or to the Commissioner of the Regional FDS in case of the renewal of the certificate of approval or registration of manufacturing business of medicinal products, etc., the certificate of register of contract manufacturing and sales business, the certificate of register of importing business, the certificate of marketing approval of manufacture, sale and importation of medicinal products required to prove their bioequivalence, the certificate of marketing approval of manufacture, sale and importation of quasi-drugs which are not subject to review of safety of efficacy and the certificate of notification of manufacture, sale and importation of medicinal products, etc.) <Revised on Sep. 25, 2015>

(4) If information on attached document under paragraph (3) can be verified through the procedure for common use of administrative information in accordance with Article 36 (1) of the Electronic Government Act, such verification may replace the submission of attachment.

Article 101 (Collection of Public Impost)

To collect a penalty under Article 34 (2) 1 of the Enforcement Decree, the Enforcement Regulation of the Management of the National Funds Act shall apply. In such instance, the payment notice shall include the information on the formal objection method and deadline.

Article101-2(Imposing penalty surcharge for manufacturing of risk pharmaceuticals)

(1) Notice of payment for penalty surcharge according to Article 34(4)(1) of the Enforcement Decree is same as Subparagraph 86 of annexed document.

(2) The application of time limit postponement on payment penalty surcharge according to Article 34(5)(1) or(2) of the Enforcement Decree is same as Subparagraph 87 of annexed document.

(3) The application of severable payment for penalty surcharge is same as Subparagraph 88 of annexed document.

(4) Besides matters prescribed in Paragraph (1) to (3), detailed matters concerning imposition and payment of penalty surcharge will be determined and notified by the Minister of Ministry of Food and Drug Safety.

Article 102 (Payment of Fees)

Fees pursuant to Article 82 of the Act shall be paid in the revenue stamp (cash or certificate proving payment), fiscal stamp or electronic cash. electronic payment through the information and communication network.

Article 102-2 (Registration Fee)

(1) The registration fee for one year pursuant to Article 82-2 shall be 5,000 won per patent claim.

(2) The registered patentee shall pay the registration fee for first year within 3 months from the date of registration.

(3) From the second year, the registered patentee shall pay the registration fee for one year within three months based on the date of registration every year. However, beginning in the second year the registered patentee can pay the fee for several years in one lump sum.

(4) The registration fee pursuant to Article 82-2 of the Act shall be paid through a revenue stamp (cash or a certificate of proof of payment in cash), certificate stamp, or electronic money/electronic payment, etc. using the information communication network.

[This Article is newly established. March 13, 2015]

Article 102-3 (Application, Etc. for Designation as a Training Institution for Professional Personnel)

(1) The application for designation pursuant to Article 34-3 (2) of the Act shall be as shown in Form No. 74-2.

(2) The "documents prescribed by the Ordinance of Prime Minister" in Article 34-3 (2) of the Act shall mean the documents in each of the following subparagraph:

1. Business plan to train professional personnel;
2. Data on the status of securing of human resources, facilities and equipment related to education and training;
3. Plan for procurement of operational expenses related to education and training;
4. Regulations on the operation of education and training

(3) The letter of designation pursuant to Article 34-3 (4) of the Act shall be as shown in Form No. 74-3.

[This Article is newly established. Sep. 25, 2015]

Article 102-4 (Request, etc. for Extension of Expiration Dates of Stockpiled Medicinal Products)

(1) The medicinal products for which the Minister of Health and Welfare may request to extend the expiration dates pursuant to Article 85-2 (2) of the Act shall be medicinal products that are stockpiled (hereinafter referred to as the “stockpiled medicinal products”) pursuant to Article 40 (1) of the Infectious Disease Control and Prevention Act.

(2) If the Minister of Health and Welfare intends to extend the expiration dates of the stockpiled

medicinal products pursuant to Article 85-2 (2) of the Act, he/she shall submit the application for extension of expiration dates of stockpiled medicinal products in Form 74-4 to the Minister of Ministry of Food and Drug Safety along with each of the following data until three months before the expiration dates of the relevant stockpiled medicinal products:

1. Quality inspection report;
2. Stability test data;
3. Materials to prove that the stockpile is stored in accordance with Schedule 1, Schedule 3 or Schedule 6;
4. Reasons for extension and data on the stockpile status;
5. Other materials that are required for the reviewed of safety, efficacy, etc. of stockpiled medicinal products, as prescribed and notified by the Minister of Ministry of Food and Drug Safety.

(3) If the request to extend the expiration dates of stockpiled medicinal products pursuant to Paragraph (2) is deemed appropriate, the Minister of Ministry of Food and Drug Safety shall issue the notice of approval of extension of expiration dates of stockpiled medicinal products in Form 74-5.

(4) The control standards for stockpiled medicinal products of which the expiration dates have been extended pursuant to Paragraph (3) shall be as follows:

1. Containers or packaging shall be marked to reflect the extended expiration dates;
2. Conduct a quality inspection every half year;
3. Comply with other matters prescribed and notified by the Minister of Ministry of Food and Drug Safety to ensure safety and efficacy.

(5) The types and requirements of the data to be submitted, control standards, and other detailed requirements pursuant to paragraphs (2) to (4) shall be determined and notified by the Minister of Ministry of Food and Drug Safety.

[This Article is newly established. Sep. 25, 2015]

Article 102-5 (Prohibition of Use of Similar Names)

"Similar names prescribed by Ordinance of the Prime Minister" pursuant to Article 87-2 shall mean pharmaceuticals, medicines, and new drugs.

[This Article is newly established. Dec. 13, 2017]

Article 102-6 (Master Plan for pharmaceutical Safety Management and Establishment of Implementation Plan)

The Minister of Ministry of Food and Drug Safety may publish the plans on MFDS official web site if the Minister establishes master plan for pharmaceutical safety management according to Article 83(4)(1) of the Act or devise implementation plan for pharmaceutical safety management according to the same Article (3).

[Newly Established 6 Dec, 2019]

Article 102-7 (Construction·Operation of Pharmaceutical Information System)

(1) The Minister of Ministry of Food and Drug Safety may form・operate working group staffed by officials, directors of public organizations or civilian experts, if the Minister deems necessary to effectively construct and operate the pharmaceutical information system(hereinafter refers to 'information system') according to 83-5(1) of the Act.

(2) The Minister of Ministry of Food and Drug Safety may include the following matters(electronic documents are included), if the Minister requests the information for the construction and operation of pharmaceutical information system according to Article 83(5)(2).

1. Matters concerning the scope of the requested information
2. Matters concerning the submission method and time limit
3. Besides the matters mentioned above, the matters which the Minister of Ministry of Food and Drug Safety deems necessary to effectively construct and operate the pharmaceutical information system.

(3) 'A person who prescribed by Ordinance of the Prime Minister'according to Article 83 (5) (2) to (3) of the Act refers to one of the following persons.

1. A manufacturing supervisor according to Article 36 of the Act(including the case to which Article 42 (5) of the Act applies mutatis mutandis)
2. A safety management supervisor according to Article 37(3) of the Act(including the case to which Article 42 (5) of the Act applies mutatis mutandis)
3. A seller of over the counter drugs according to Article 44(2)(1) of the Act

(4) The Minister of Ministry of Food and Drug Safety shall entrust Korea Institute of Drug Safety & Risk Management(KIDS) with maintenance of pharmaceutical information system pursuant to the former part of Article 83(5)(3) of the act. In this case, the president of the KIDS shall report matters concerning project status and financial enforcement statement to the Minister of Ministry of Food and Drug Safety.

Article 102-8 (Methods and Procedures for Disclosure of Review Results) (1) "Drugs prescribed by the Ordinance of the Prime Minister" under Article 88-2 (1) of the Act refers to finished drugs.

② If the Minister of Ministry of Food and Drug Safety intends to disclose the results of review pursuant to Article 88-2 Paragraph 1 of the Act, he or she may listen to their opinions by notifying the person who has obtained marketing approval for the drug in advance of the results of the review.

③ When the Minister of Ministry of Food and Drug Safety intends to disclose the results of review pursuant to Article 88-2 Paragraph 1 of the Act, the date on which marketing approval for manufacturing, sales and import is granted (including facility conditional approval or marketing conditional approval) or within 180 days from the date of accepting marketing approval for manufacturing, sales and import notification, the results of the review shall be disclosed on the Internet website operated by the Minister of Ministry of Food and Drug Safety.

[newly established on January 20, 2022]

Article 103 (Succession to Status of Manufacturer and Others)

(1) A person who declares the succession to status of manufacturer and others pursuant to Article 89 (3) of the Act shall submit the succession declaration of Form No. 75 (including electronic declaration) with the relevant approval, .register, or designation certificates, or approval document of clinical trial plan or a letter of compliance and the following documents attached (including electronic documents) to the Minister of Ministry of Food and Drug Safety (or to the Commissioner of the Regional FDS for a manufacturer of medicinal products, etc., a contract manufacturing and sales business person, a marketing authorization holder of quasi-drugs which are not subject to review of safety and efficacy and a person who has registered manufacture, sale and importation of medicinal product).

1. Copies of documents proving the transfer assumption (limiting to the case of transfer);
2. Family relationship certificate in accordance with Article 15 (1) 1 of the Act on the Registration, Etc. of Family Relationship and document proving the inheritor (limiting to the case of inheritance);
3. Other documents proving the succession to the status of manufacturer and others while considering the nature of the succession;
4. Medical certificate proving that the person to which the status is transferred does not fall into the reasons for disqualification pursuant to subparagraphs 1 and 3 of Article 5 of the Act (limiting to the succession to status of manufacturer and others pursuant to Article 89 (1) of the Act).

(2) On receipt of the declaration under paragraph (1), the Minister of Ministry of Food and Drug Safety shall verify the certificate of corporation registration (limiting to corporations) through the procedure for common use of administrative information in accordance with Article 36 (1) of the Electronic Government Act.

(3) If a person who intends to declare the succession to status of manufacturer and others pursuant to paragraph (1) intends to change the name or company name of the medicinal products manufacturing site, a contract manufacturing and sales business site, clinical trial institution, those who received the approval for clinical trial plan, clinical trial sample analysis institution or non-clinical trial institution or to change the names of medicinal products, he/she may declare such changes together. In such instance, such declaration will be regarded as the application for approval or designation amendment or the amendment register in accordance with Article 11, Article 34 (6), Article 35 (7) and Article 37 (6). <Revised on Aug. 20, 2014>

(4) The person who intends to declare the succession pursuant to paragraph (1) shall pay the fee as notified by the Minister of Ministry of Food and Drug Safety.

Article 104 (Review of Regulatory Requirements)

The Minister of Ministry of Food and Drug Safety shall review the following points every 3 years based on the specified dates (meaning that the review shall be completed before the same date in the every 3rd year) to determine their appropriateness and to take actions for improvement and others.

1. Submission, implementation and retention of risk management plan under Article 4, Sub-paragraph 11, Article 47 and Article 49: January 1, 2014;
2. Testing of raw materials used in the manufacture of quasi-drugs on their receipt under Article 43, Paragraph (1), Subparagraph 5: January 1, 2014;

2 of 2. Matters to be observed by the safety management manager pursuant to Article 47 and Annex 4-3: January 1, 2023

2 of 3. Matters to be observed by manufacturers of pharmaceuticals, etc. under Article 48 (manufacturer compliance requirements under subparagraphs 1, 5, 5-2, 6, 9, 9-2, 11, and 14 of the same Article are excluded): January 1, 2023

3. Obligations which have to be fulfilled by a person who intends to manufacture pharmacy medications or dispensary medications: January 1, 2014;
4. Preparation of standard operating procedures for medicinal products containing raw materials of animal origin (limiting to injections) under Annex 1: January 1, 2014.
5. Administrative disposition standards under Article 95 and Annex 8(II. subparagraphs 2, 3, 15 e, 21, 22, 25 c, 28 and 32 of Individual standards are excluded): January 1, 2023

[Full Revised on Aug. 21, 2014]

Addendum <No. 1848, Dec 29, 2022>

Article 1 (Enforcement Date) This regulation shall take effect from the date of promulgation.

Article 2 (Applicability to Processing Period of Application for Registration of Drug Substances) The amended regulations of Annex Form No. 16 (applicable only to the amended part regarding processing period) applies to application for registration of drug substances or registration of changes to registration matters of drug substances after this regulation enters into force.

Article 3 (Transitional Measures Regarding the Determination of Conformity of Herbal Medicinal Herbs) A person who has received conformity for herbal medicines pursuant to the previous regulations prior to the enforcement of this Regulation shall receive the conformity determination in accordance with the amended provisions of Article 48-2 by December 31, 2025.