Article Content

Title Pharmaceutical Affairs Act Enforcement Rules Ch

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Category Ministry of Health and Welfare (衛生福利部)

Article 1 These Enforcement Rules are adopted pursuant to Article 105 of the Pharmaceutical Affairs Act ("the Act").

Article 2 Terms used in Article 7 of the Act are defined as follows:
1. New composition: a newly invented composition that can be used for pharmaceutical purposes.
2. New therapeutic compound: an already approved drug with new medical efficacy in terms of new indications, reduced side effects, improved therapeutic strength, improved therapeutic period, or altered dosage, or a compound prepared from two or more already approved compositions whose medical efficacy is superior to either of the individual drug compositions.
3. New method of administration: An altered method of administration for an already approved drug.

Article 3 The term "medicines to be prescribed by physicians" in Article 8 of the Act means a medicine, following its examination and approval by the central competent health authority, for which the drug permit license states that it must be prescribed by a physician or is restricted to use by physicians.

Article 4 The term "inspection" as used in the Act means the examination of matters in respect of whether a drug has undergone registration and market approval, and whether the drug conforms with the original market inspection and approval or other relevant provisions.
The term "testing" as used in the Act means the chemical testing and assessment of the state, ingredients, quality, quantity, or strength of a drug, or the assessment of a medical device through chemical, physical, mechanical, or materials testing.

Article 5 The term "manufactured without prior approval" as used in Article 20, subparagraph 1 does not include drugs under research or in trial production that are not for sale.
The drugs of the preceding paragraph shall be ones for which there is a record of research or trial production and are restricted to those that are not packaged as a marketable product.

Article 6 The term "drug imported without prior approval" in Article 22, subparagraph 2 of the Act means that no drug permit license allowing import has been approved and issued by the central competent health authority in accordance with Article 39 of the Act.

Article 7 The term "use" in Article 23, subparagraph 1 of the Act means normal, reasonable use in accordance with labeling or usage instructions.

Article 8 The term "labels" in Article 25 of the Act includes text, images, or markings that appear directly on a medical device as indications.

Article 9 The matters to be registered by a pharmaceutical firm pursuant to Article 27, paragraph 21 of the Act are as follows:
1. The type of pharmaceutical firm being registered.
2. The lines of business of the firm.
3. The name of the firm.

4. The firm's address.
5. The firm's responsible persons.
6. The firm's drug administration, manufacturing supervision, or technical personnel.
7. Other required matters for registration.

Article 10 Those applying for registration as a pharmaceutical firm in accordance with Article 27, paragraph 1 shall fill out an application form, submitting it together with a licensing fee and the documents listed below, for approval by the competent health authority of their special municipality or county (or county-level city):
1. The professional licenses or certification documents of the drug administration, manufacturing supervision, or technical personnel that the firm is required to hire under the provisions of the Act.
2. For a pharmaceutical firm organized as a company, photocopies of the firm's corporate registration and articles of incorporation.
3. For a seller of drugs and medical devices, the firm's business address and a basic floor plan showing the premises (the drug storage warehouse) and principal equipment.
4. For a manufacturer of drugs or medical devices, the firm's factory registration certificate and a photocopy of the same, except when the firm is exempt from factory registration under the Factory Management Act.
5. Other documents required by the special municipality or county (or county-level city).
For a newly established pharmaceutical firm organized as a company, the competent health authority may first issue establishment permit documents to the firm, then issue a pharmaceutical firm permit license to the firm after it obtains its corporate registration or factory registration documents.

Article 11 In any application for registration as a pharmaceutical firm, the provisions of Articles 14 through 18 of the Act shall be followed with respect to which type of pharmaceutical firm the application is for and the lines of business to be stated in the registration.
When a seller of western drugs is under the management of a resident assistant pharmacist, the listing of its lines of business shall note that it is not a seller of narcotic drugs.
When a pharmaceutical firm engages in the business of radiopharmaceuticals, it shall apply for and receive approval in accordance with relevant laws and regulations before commencing sale of those items.

Article 12 When a drug manufacturer engages in the wholesaling and exporting of its own products, the importing of raw materials for its own use, or the concurrent retailing of its own products in accordance with Article 16 of the Act, and does so at the same location at which it manufactures and processes drugs, those businesses may be concurrently managed by its manufacturing supervisor. When the pharmaceutical firm, however, concurrently engages in the sale of products other than its own products or establishes a separate place of business to engage in any of the foregoing businesses, it shall employ separate management personnel for those respective purposes, and shall register as a pharmaceutical firm that is a seller of drugs or medical devices.
When a drug manufacturer, in accordance with Article 58 of the Act, contracts another manufacturer to manufacture drugs, the wholesaling, exporting, and retailing of those drugs may take place in accordance with the fore part of the preceding paragraph.

Article 13 The categories of medical devices and the qualifications of the related technicians that a manufacturer of medical devices is required to employ, pursuant to Article 32 of the Act, are as follows:
1. Manufacturers of general medical equipment, clinical examination equipment, and biological materials and equipment shall employ, as manufacturing supervisor at its factory, a full-time resident technician who is a graduate of the science, engineering, medicine, or agriculture department at the undergraduate or graduate level of a domestic public or accredited private junior college or higher-level educational institution, or of a foreign junior-college or higher level institution recognized by the Ministry of Education.
2. Manufacturers of antiseptic contact lens cleaning solutions (or tablets), organ transplant preservation solutions, health materials, or feminine sanitary napkins shall employ a full-time resident pharmacist as manufacturing supervisor at the factory.

Article 14 A pharmaceutical firm's permit license or a pharmacy's pharmacy license shall be hung at a conspicuous location at its place of business.

Article 15 Matters relating to the "amendment of registration" that shall be carried out in accordance with Article 27, paragraph 1 of the Act include amendments to the content of a pharmaceutical firm's registration and the voluntary suspension, resumption, or termination of business.
To carry out amendment of registration, a pharmaceutical firm must apply to the competent health authority that originally approved its registration within 15 days from the date of occurrence of a change in any matter requiring amendment of registration under the preceding paragraph.

Article 16 When a pharmaceutical firm amends its registration, except for registering an amendment for a change of address, it shall first apply to the competent health authority to amend the registration of its business address. Amendments to its registration pertaining to other company organization or business registration matters shall first be carried out with the relevant competent authority for commercial matters.

Article 17 When a pharmaceutical firm has employed a person for drug administration or manufacturing supervision in accordance with Articles 28 or 29 of the Act or employed a technician in accordance with Articles 21 or 32 of the Act, and that person is unable to perform their duties due to dismissal, resignation, or some other reason, and no other such person has yet been employed, the pharmaceutical firm shall suspend business operations and apply for suspension or termination of its registration.

Article 18 A pharmacist, assistant pharmacist, or Chinese medicine doctor employed by a seller of drugs in accordance with Article 28 of the Act, or a pharmacist or an assistant pharmacist that personally manages the business of a pharmacy in accordance with Article 19 of the Act, shall be personally present to conduct business at the firm's place of business. When that person is not present at the place of business, a sign clearly indicating that fact shall be hung on the door.

Article 19 (deleted)

Article 20 (deleted)

Article 21 (deleted)

Article 22 (deleted)

Article 22-1 To apply for the importation of active pharmaceutical ingredients for the trial production of a drug in accordance with Article 39, paragraph 2 of the Act, an application fee shall be paid and an application form, along with the following materials, submitted to the central competent health authority for approval:
1. The pharmaceutical firm's permit license.
2. A written trial production plan.
3. The factory registration documents issued by the Ministry of Economic Affairs. Research and development organizations are exempt from this requirement.
4. When another pharmaceutical firm is contracted to handle the importation of active pharmaceutical ingredients for trial production of a drug, the letter of instruction and the pharmaceutical firm permit licenses of the contracting party and the contractor are required.

Article 23 (deleted)

Article 23-1 The central competent health authority may engage a health foundation or other related group or organization to perform reviews of academic research, safety and clinical trials, and other technical materials in connection with the market approval of drugs.

Article 24 The items required for the registration and market approval of a drug, as referred to in Articles 39 and 40 of the Act, are as follows:
1. The Chinese and foreign-language name of the drug.
2. The drug's prescription and dosage form.
3. The components, materials, structure, and specifications of medical devices.
4. The drug's labeling, usage instructions, and packaging.
5. The direct packaging of the drug.
6. The indications, efficacy, properties, method of use, amount used, and type of the drug.
7. The manufacturing method, the test specifications, and method of testing of the drug.
8. The name of the pharmaceutical firm.
9. The name and address of the factory that produces the drug.
10. Other items designated for registration of the drug by the central competent health authority.

Article 25 (deleted)

Article 26 (deleted)

Article 27 For drugs produced in Taiwan, the labeling, usage instructions, and packaging shall be primarily in Chinese. Any appended text in a foreign language shall be smaller than the Chinese.
Chinese usage instructions shall be appended to foreign imported drugs, and both their labeling and packaging shall bear the product's name, type, and registration number, and the name and address of the importing pharmaceutical firm, in Chinese. The period of validity or shelf life of the drug shall be labeled in Chinese or by the use of a commonly recognized labeling method. The lettering of the Chinese product name may not be smaller than the lettering of the foreign language name.

Article 28 When a change in the name of a pharmaceutical firm involves a transfer of rights, applications [for amendment of registration] shall be submitted by both parties.

Article 29 (deleted)

Article 30 (deleted)

Article 31 When, in response to the demands of buyers in the region of export, the name, labeling, usage instructions, or packaging of exported drugs must be changed or a foreign language text must be appended, an application shall be filed with two copies of the details of the required changes attached, for review and approval by the central competent health authority.
No drug which, pursuant to the preceding paragraph, has had its name, labeling, usage instructions, or packaging changed or has had a foreign language text appended may be sold domestically.

Article 32 (deleted)

Article 33 The term "may not purchase or sell," in Article 49 of the Act, includes the sale of drugs to other than pharmacies, pharmaceutical firms, or medical care institutions. However, this rule does not apply to single-herb Chinese medicines that are manufactured by manufacturers of Chinese medicines for both medical and dietary purposes and wholesaled to food manufacturers as food raw materials.

Article 34 After the repackaging of imported active pharmaceutical ingredients in accordance with Article 53, paragraph 2 of the Act has been conducted by an importing pharmaceutical firm that meets the good manufacturing practice standards for drugs, the firm shall fill out an application form, accompanied by a photocopy of the drug permit license, a copy of the import declaration approved and issued by customs, the original manufacturer's certificate of analysis, the method of testing, and other designated documentation, and apply for recordation with the central competent health authority.
Repackaged active pharmaceutical ingredients may only be sold to drug manufacturers; the labeling used shall indicate the following matters:
1. The manufacturer's name and address.
2. The product name and registration number.
3. The efficacy of the drug and its indications.
4. The lot number.
5. The name and address of the repackaging pharmaceutical firm.
6. The date of repackaging.
7. The date of manufacture and the period of validity or shelf life.
8. Other matters that shall be indicated in accordance with relevant provisions.
Subparagraph 7 of the preceding paragraph does not apply when the central competent health authority, by public announcement, has ordered exemption from the requirement to indicate the matters set out in that article.

Article 35 The containers, labeling, usage instructions, and packaging of biological drugs shall indicate the items set out in Article 75 of the Act. Those that contain preservatives shall be labeled with the amount of preservative content.

Article 36 When, during the inspection and batch-sealing procedures required under Article 74 of the Act, review or test results indicate non-conformance with standards, then in the case of a foreign imported drug, personnel shall be dispatched by the competent health authority of the special municipality or county (or county-level city) to oversee return shipment of the drugs within a specified period by the original importer; in the case of domestically manufactured drugs that can be used after re-modification, personnel shall be dispatched by the competent health authority of the special municipality or county (or county-level city) to oversee their re-

modification within a specified period by the original manufacturer. If the return shipment or re-modification cannot be accomplished within that time period, or if re-modification is not possible, the drugs shall be destroyed.

Article 37 When any circumstance under Article 80, paragraph 1, subparagraphs 1 through 4 of the Act applies to a drug, the pharmaceutical firms, pharmacies, and medical care institutions concerned shall immediately cease their importation, manufacture, wholesaling, display, preparation, and retailing of the drug from the date of public announcement or from a date determined in accordance with the law. Any firm that manufactures or imports the drug shall recall the drugs from the market within the period specified for that purpose, and shall dispose of them, along with the drugs in their stock, in accordance with Article 79 of the Act. The recall period, which at most may not exceed 2 months, shall be determined by the central competent health authority based on the nature of the individual case.

When any circumstance under Article 80, paragraph 1, subparagraphs 5 or 6 of the Act applies to a drug, the drug may not be sold until the firm that manufactures or imports the drug, within 6 months from the date of expiration of the drug permit license or from the date on which the change in packaging, labeling, or usage instructions is approved, has recalled the product from the market and delivered it, along with any product in their stock, to be examined by and receive the seal of the competent health authority of the special municipality or county (or county-level city).

Prior to carrying out recall of a drug, a manufacturer or importer shall formulate a written recall plan, setting out the recall procedure, time period, the deadline for filing a report on the recall results for recordation, and other related matters. The recall plan shall be submitted to the central competent health authority for recordation, and the recall shall then be carried out in accordance with the plan; after the recall has been completed, the report on results of the recall shall be prepared and submitted to health authorities at all levels for recordation.

Article 38 To take enforcement action against counterfeit drugs, misbranded drugs, prohibited drugs, defective medical devices, or medical devices manufactured or imported without prior approval, the competent health authority of a special municipality may establish an investigation and enforcement center; a county (or county-level city) may establish an investigation and enforcement team.

Article 39 If counterfeit drugs, misbranded drugs, prohibited drugs, defective medical devices, or medical devices manufactured or imported without prior approval are seized in response to an informant's report, a reward may be issued by the competent health authority of the special municipality or county (or county-level city) based on the point system below:

1. Reports of the manufacture or importation of counterfeit drugs, prohibited drugs, or medical devices manufactured or imported without prior approval: 4 to 10 points.
2. Reports of the wholesale resale (or transfer) of counterfeit drugs, prohibited drugs, or medical devices manufactured or imported without prior approval: 2 to 5 points.
3. Reports of the retailing, shipment, storage (or acceptance for storage), a person acting as a broker for, or the display with intent to sell of counterfeit drugs, prohibited drugs, or medical devices manufactured or imported without prior approval: 2 to 3

points.
4. Reports of the manufacture, importation, or sale of misbranded drugs or defective medical devices: 2 to 3 points.
The monetary amount correlated with each point will be determined by the competent health authority of the special municipality or county (or county-level city) as it deems appropriate under the circumstances, and it shall also make budgetary allocations for that purpose. When necessary, the central competent health authority may allocate funds to subsidize rewards for seizures.

Article 40 When a case under the preceding Article is jointly reported by two or more persons, the reward shall be collected jointly by the persons who made the original report. If two or more persons separately report a case and the particulars of the case are the same, the reward shall be issued to the first person to make the report; if the order of reporting cannot be determined, the reward shall be divided equally among the persons who made reports.

Article 41 The standards for rewards to individual informants shall apply mutatis mutandis to those who assist enforcement authorities in seizing counterfeit drugs, misbranded drugs, prohibited drugs, defective medical devices, or medical devices manufactured or imported without prior approval.

Article 42 When a reward is to be issued in accordance with these Enforcement Rules, an application for the reward, stating the facts of the matter, shall be made by the enforcement authority that seized the counterfeit drugs, misbranded drugs, prohibited drugs, defective medical devices, or medical devices manufactured or imported without prior approval. Multiple rewards may not be issued to a person who simultaneously qualifies for a reward under both these Enforcement Rules and other laws or regulations.

Article 43 The name of an informant or a person who assists in the seizure of counterfeit drugs, misbranded drugs, prohibited drugs, defective medical devices, or medical devices manufactured or imported without prior approval shall be kept confidential, and may not be divulged.

Article 44 No publication or dissemination of an advertisement for a drug may take place until a pharmaceutical firm with a drug permit license has filled out an application form and submitted it to the central competent health authority or the competent health authority of the special municipality or county (or county-level city) along with photocopies of the drug permit license and the approved labeling, usage instructions, and packaging, the content of the advertisement, and a review fee, and the given health authority has reviewed and approved the above matters.

Article 45 Texts and images used in a drug advertisement shall be limited to the name of the drug, its dosage form, prescription content, usage quantity, usage method, efficacy, guidelines, and packaging, and the name and address of the manufacturer, as initially approved by the central competent health authority.
The efficacy stated in the text of an advertisement for Chinese medicine materials shall be limited to the efficacy stated in the Compendium of Materia Medica.

Article 46 The name of the firm and the number of its drug permit license and the advertisement approval document shall be published simultaneously or disseminated together with any drug advertisement.

Article 47 When any of the following occurs in drug advertising content, that content shall be deleted or its approval shall be denied:

1. Content involving efficacy related to sexual intercourse.
2. The use of methods likely to encourage drug abuse, such as exchanges of drug containers for prizes or the provision of incentives.
3. Any representation that use of a drug will cure a particular disease or will improve a person's health or constitution in a particular area, or the creation of false or misleading scenarios as a means of publicizing the drug.
4. Exaggeration of a drug's efficacy or safety.

Article 48 (deleted)

Article 49 (deleted)

Article 50 "Urgent need of medical treatment services," as used in Article 102, paragraph 2 of the Act, means circumstances in which a physician at a medical care institution, due to urgent need for medical care measures, must immediately use a drug.

Article 51 (deleted)

Article 52 (deleted)

Article 53 The forms of documents required by the Act or by these Enforcement Rules shall be defined by the central competent health authority.

Article 54 These Enforcement Rules shall take effect from the date of their issuance.